IMPACT OF OUR ANTITRUST LAWS ON COMMUNITY PHARMACIES AND THEIR PATIENTS

HEARING

BEFORE THE

TASK FORCE ON ANTITRUST
AND COMPETITION POLICY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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OCTOBER 18, 2007

IMPACT OF OUR ANTITRUST LAWS ON COMMUNITY PHARMACIES AND THEIR PATIENTS

THURSDAY, OCTOBER 18, 2007

HOUSE OF REPRESENTATIVES,
TASK FORCE ON ANTITRUST
AND COMPETITION POLICY
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The Task Force met, pursuant to notice, at 9:40 a.m., in Room 2141, Rayburn House Office Building, the Honorable John Conyers (Chairman of the Task Force) presiding.

Present: Representatives Conyers, Lofgren, Jackson Lee, Waters, Sutton, Sherman, Weiner, Chabot, Keller, Issa, and Feeney.

Staff Present: Stacey Dansky, Majority; Stewart Jeffries, Minority Counsel; and Benjamin Staub, Professional Staff Member.

Mr. CONYERS. Good morning, ladies and gentlemen.

The Committee has joined me here, the Antitrust Task Force hearing, to examine the impact of our antitrust laws on community pharmacies and their patients. I don't think anyone in the Congress has not been visited by their constituents on this matter.

And today we delve into an aspect of the health care industry that is frequently overlooked but, in my mind, may be one of the most important parts of the whole system, because pharmacies serve as the interface between consumers and their medication, a vital link. And independent pharmacies provide necessary and important services to patients all over the country and in places where, without them, there might not be any service for those consumers that might need it.

Now, there is a common agreement that the health care system is in trouble. It has become so expensive that almost 50 million Americans don't have coverage of any kind, and some 20 million or more that do aren't covered for the right thing that they unfortunately find out when they go into their doctor or hospital.

According to the Institute of Medicine, some 18,000 people die in this country each year because of lack of health care. What I am saying really is they don't have the insurance that would allow them to be served by a doctor, clinic or a hospital. And we pay, in this country, on a per capita basis, more for health care, receive less from health care, and experience less satisfactory outcomes than many other countries in the world that have a universal health care system.

Independent pharmacies are also suffering in today's health care marketplace. We are told, and we will hear here today, how they are being driven out of business because they can't compete with large retail pharmacies and cannot survive with the low reimbursement rates that are given to them now.

So, given the importance of the human interaction between the patient, the doctor and the pharmacist, the ability to ask questions about drugs and get prescriptions filled immediately is a very important consideration. A substantial part of the crisis in our health care is the cost of prescription drugs and the prescription drug program currently in place.

According to a report issued by the premiere Oversight Committee in the House, it said that privatizing the delivery of the drug benefit has enriched the drug companies and insurance industry at the expense of seniors and taxpayers. The report concluded that insurers participating in Medicare Part D do not cover prescription drugs as efficiently as other programs do, and that Medicare Part D beneficiaries and taxpayers could be saving billions of dollars per year if seniors got their Part D benefits directly from Medicare instead of through insurance companies.

The report went on to conclude that administrative costs sometimes run six times higher in private health insurance companies than in Medicare's traditional fee-for-service program. Approximately $4.6 billion went into administrative costs and other expenses in fiscal year 2007, and a billion dollars of that amount was steered toward insurance company profits.

The Chairman of the Oversight Committee, the gentleman from California, Henry Waxman, stated further that the program inflated administrative costs and meager drug rebates, and that that will cost taxpayers and seniors $15 billion in this year alone. So, based on that report, it seems clear that, because of Medicare Part D, small pharmacies have suffered because of higher administrative costs, approximately some $15 billion a year. And that has prevented the reimbursement of pharmacies at a higher rate than the traditional PBMs do now. A proposed solution is to allow independent pharmacies to collectively negotiate for a better reimbursement rate.

One of the Members of this Committee, and present here today, Anthony Weiner of New York, has put forward a proposal to alleviate some of the problems facing independent pharmacies and has a measure, H.R. 971, which we will hear more about.

[The bill, H.R. 971, follows:]

I

110TH CONGRESS
1ST SESSION

H. R. 971

To ensure and foster continued patient safety and quality of care by making the antitrust laws apply to negotiations between groups of independent pharmacies and health plans and health insurance issuers (including health plans under parts C and D of the Medicare Program) in the same manner as such laws apply to protected activities under the National Labor Relations Act.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2007

Mr. WEINER (for himself and Mr. MORAN of Kansas) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To ensure and foster continued patient safety and quality of care by making the antitrust laws apply to negotiations between groups of independent pharmacies and health plans and health insurance issuers (including health plans under parts C and D of the Medicare Program) in the same manner as such laws apply to protected activities under the National Labor Relations Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Community Pharmacy Fairness Act of 2007".

SEC. 2. APPLICATION OF THE ANTITRUST LAWS TO INDEPENDENT PHARMACIES NEGOTIATING WITH HEALTH PLANS.

(a) IN GENERAL.—Any independent pharmacies who are engaged in negotiations with a health plan regarding the terms of any contract under which the pharmacies provide health care items or services for which benefits are provided under such plan shall, in connection with such negotiations, be entitled to the same treatment under the antitrust laws as the treatment to which bargaining units which are recognized under the National Labor Relations Act are entitled in connection with activities described in section 7 of such Act. Such a pharmacy shall, only in connection with such negotiations, be treated as an employee engaged in concerted activities and shall not be regarded as having the status of an employer, independent contractor, managerial employee, or supervisor.

(b) PROTECTION FOR GOOD FAITH ACTIONS.—Actions taken in good faith reliance on subsection (a) shall not be the subject under the antitrust laws of criminal sanctions nor of any civil damages, fees, or penalties beyond actual damages incurred.

(c) NO CHANGE IN NATIONAL LABOR RELATIONS ACT.—This section applies only to independent pharmacies excluded from the National Labor Relations Act. Nothing in this section shall be construed as changing or amending any provision of the National Labor Relations Act, or as affecting the status of any group of persons under that Act.

(d) EFFECTIVE DATE.—The exemption provided in subsection (a) shall apply to conduct occurring beginning on the date of the enactment of this Act.

(e) LIMITATION ON EXEMPTION.—Nothing in this section shall exempt from the application of the antitrust laws any agreement or otherwise unlawful conspiracy that excludes, limits the participation or reimbursement of, or otherwise limits the scope of services to be provided by any independent pharmacy or group of independent pharmacies with respect to the performance of services that are within their scope of practice as defined or permitted by relevant law or regulation.

(f) NO EFFECT ON TITLE VI OF CIVIL RIGHTS ACT OF 1964.—Nothing in this section shall be construed to affect the application of title VI of the Civil Rights Act of 1964.

(g) NO APPLICATION TO SPECIFIED FEDERAL PROGRAMS.—Nothing in this section shall apply to negotia-

tions between independent pharmacies and health plans pertaining to benefits provided under any of the following:

(1) The Medicaid Program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(2) The State Children's Health Insurance Program (SCHIP) under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.).

(3) Chapter 55 of title 10, United States Code (relating to medical and dental care for members of the uniformed services).

(4) Chapter 17 of title 38, United States Code (relating to Veterans' medical care).

(5) Chapter 89 of title 5, United States Code (relating to the Federal employees' health benefits program).

(6) The Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(h) DEFINITIONS.—For purposes of this section:

(1) ANTITRUST LAWS.—The term "antitrust laws"—

(A) has the meaning given it in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act

(15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

(B) includes any State law similar to the laws referred to in subparagraph (A).

(2) HEALTH PLAN AND RELATED TERMS.—

(A) IN GENERAL.—The term "health plan"—

(i) means a group health plan or a health insurance issuer that is offering health insurance coverage;

(ii) includes a prescription drug plan offered under part D of title XVIII of the Social Security Act and a Medicare Advantage plan offered under part C of such title; and

(iii) includes any entity that contracts with such a plan or issuer for the administering of services under the plan or coverage.

(B) HEALTH INSURANCE COVERAGE; HEALTH INSURANCE ISSUER.—The terms "health insurance coverage" and "health insurance issuer" have the meanings given such terms under paragraphs (1) and (2), respectively, of section 733(b) of the Employee Retire-

ment Income Security Act of 1974 (29 U.S.C. 1191b(b)).

(C) GROUP HEALTH PLAN.—The term "group health plan" has the meaning given that term in section 733(a)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(a)(1)).

(3) INDEPENDENT PHARMACY.—The term "independent pharmacy" means a pharmacy which is not owned (or operated) by a publicly traded company. For purposes of the previous sentence, the term "publicly traded company" means a company that is an issuer within the meaning of section 2(a)(7) of the Sarbanes-Oxley Act of 2002 (15 U.S.C. 7201(a)(7)).

○

Mr. CONYERS. But such an arrangement would require a special exemption to our antitrust laws in that regard. And so, while I am generally disinclined toward exemptions to antitrust laws, there could be particular circumstances where a carefully crafted exemption could be warranted.

And so, today, we hear from witnesses to discuss whether such an exemption in the case of independent pharmacies is warranted. And these are a few of the crucial questions that we have gathered here today to discuss with our friends in the pharmacy industry. They waited a long time for this hearing, and I am glad that we are here to oblige you in that request this morning.

And I'd like now to ask Ric Keller, who is our acting Ranking minority Member, to begin his discussion of this matter before us. The gentleman from Florida is recognized.

Mr. KELLER. Thank you very much, Mr. Chairman. And I want to especially want to thank you for convening this hearing on the Task Force on Antitrust and Competition Policy.

One thing I have to correct that you said that I have a little disagreement with, you referred to the Government Reform Committee as the premiere oversight Committee in Congress with——

Mr. ISSA. And rightfully so.

Mr. KELLER. With you at our leadership, we kind of think the Judiciary Committee is the premiere oversight Committee in Congress here. But that will probably earn me a subpoena from Mr. Waxman shortly.

I want to thank all of you for being here today.

Today's hearing on the impact of the antitrust laws on community pharmacists reflect a familiar theme in the Antitrust Task Force hearings, namely, how did the antitrust laws balance the needs of large companies on one hand with the needs of smaller companies on the other?

In today's hearing, the smaller companies are the independent pharmacies. For many years, they felt that the actions of the large companies—in this case, the larger chain stores, the HMOs and now pharmacy benefit managers, or PBMs—have been making it difficult for them to compete. They feel that the PBMs, which they claim cover almost 95 percent of all prescription drug purchases in this country, exercise market power of the independent pharmacies.

They say that market power, in turn, allows the PBMs to dictate "take it or leave it" reimbursement contracts with the independent pharmacies, and that those low reimbursement rates are driving many of the independent pharmacies out of business. To combat this perceived market power, the independent pharmacies claim that they need an antitrust exception to allow them to negotiate effectively with the PBMs.

In contrast, the PBMs feel that they are lowering prices for the American consumer. Specifically, they argue that volume discounts help seniors get lower prices for their prescription drugs. They claim that independent pharmacies can negotiate some terms of the reimbursement contracts already. And they, along with the Federal Trade Commission, have expressed concern that allowing independent pharmacies to have an antitrust exemption would

allow the pharmacies to engage in price-fixing arrangements or boycotts that could hurt consumers.

To that end, PBMs commissioned a study by Charles River Associates that shows that an antitrust exemption can cost consumers as much as $29.6 billion over 5 years. That number includes 6.4 billion under the Medicare Part D prescription drug plan.

The Supreme Court has observed that the antitrust laws exist to protect competition, not competitors. It is therefore incumbent upon us to examine this issue to see whether a legislative fix is absolutely necessary. Certainly, Congress should be mindful of the role that small business plays in our communities and in our economy, and should do everything it can to promote those businesses. At the same time, Congress must also be aware of the cost of its actions on the American consumer and the critical need for senior to have access to low-cost prescription drugs.

I look forward to hearing from all of our witnesses on this topic today. Let me just explain that I am personally very interested in what each and every one of you have to say and will read your statement. I have a markup at the exact same time, which I will have to go to and fro. And if I am not here, it is not that I am not interested, but just required to be elsewhere temporarily. But thank you very much for being here today.

And, Mr. Chairman, I yield back the balance of my time.

Mr. CONYERS. Thank you, Mr. Ric Keller.

The Chair is going to recognize Mr. Weiner, Mr. Darrell Issa and, just briefly, the gentleman from Ohio, Mr. Chabot. And we begin with the distinguished gentleman from New York.

Mr. WEINER. Thank you, Mr. Chairman, and I appreciate your calling this hearing and, frankly, organizing the Committee as it is, that you, as the Chairman, will be looking seriously at antitrust issues, because I think there are myriad issues that we need to understand a lot better around here.

You know, with all of the complicated things that are going on in health care and all of the debates that we're having—do we want larger government solutions or more private-sector solutions; do we want a business-based structure or a single-payer system, like Mr. Conyers and I have proposed—of all of the things we have disagreement on, very rarely, if ever, does anyone ever stop any of us in our communities and say, "Boy, you have got to do something to wipe out those neighborhood pharmacists." Very rarely do we hear people complain about that man or woman behind the counter in our neighborhood shopping strips, in our towns and villages, because, frankly, with more and more of the challenges facing consumers with health care, more and more of the responsibility that should be perhaps placed elsewhere is being laid on the counter of our neighborhood pharmacists. They are being asked to wrestle with Part C and now Part D.

I would argue that when Medicare Part D was initiated and started to roll out that pharmacists should have been paid as if they were civil servants for all the questions that they had to answer, all the details they had to explain, all of the combinations and permutations. It was not uncommon for someone to call up my office, ask a question about Part D, still have a little bit of concern

and say to one of my staffers, "That's okay. I'll just ask my pharmacist the rest."

And so, we have to realize that it is imperative on the part of us in Congress to make sure that that element of our health care system survives. Not only are we failing at that, but we are making it, every single day, more and more difficult for community pharmacists. You know, the changes that we made in reimbursements, the changes that we made in regulations have made it more and more difficult for neighborhood pharmacists to survive.

I did a study of New York City in 2003, and I looked at from 1990 to 2003—the data is a little bit dated by now—1990 to 2003. And we found out that, of the 1,600 community pharmacists, we had a 30 percent drop in that period, from 1990 to 2003, while the chain pharmacies had had a 263 percent increase. Now, what is happening is the chain pharmacies, as they grew stronger and stronger and their ability to compete was more and more consolidated, the neighborhood pharmacists disappeared.

So what is it that can we do? Well, there are some things that we can do. We can obviously go back and revisit the reimbursement rates, and I think we are going to in the guise of another Committee. But one of the easiest things that we can do is allow our common sense, meaning common among Democrats and Republicans alike, that competition has a way of helping solve these problems in the benefit of the consumer.

If we allow individual neighborhood pharmacies not just to operate as islands, but to be able to work together to negotiate with the big PBMs—and you can argue both ways that PBMs might save money, it might cost service, but that's the reality of the system that we have now, that the PBMs hold a lot of cards; the HMOs hold a lot of cards. And the chain stores do this every day. The chain stores, whether they're Rite Aid or Walgreens or Wal-Mart, they get together and they say to the PBMs, "Look, because we have 200, 300, 400 stores, we're going to negotiate for lower prices."

What my legislation does—and it is sponsored by Democrats and Republicans, like Mr. Coble was a sponsor in the last Congress and in this one; the bipartisan Small Pharmacy Coalition that we formed here in the Congress supports it—what we're saying is, listen, let's let these neighborhood guys band together and do their best to compete.

Now, are 20 or 30 in central Florida going to be able to band together and have the heft of a Wal-Mart? Probably not. But it would give them a little bit more advantage that they are not going and negotiating for prices for one person, they are going for five or six or seven.

Now, I have seen a study—and Mr. Keller, who laid out the issues here quite well that we have to confront—that said, well, this might mean added costs. Well, if that is the argument, then you have got to tell me why we allow competition anywhere. Maybe we should just allow the benevolence of the PBMs to just look out for us all and hope that it's in our best interests.

We are not seeing saying who should win or lose. What we are saying is that the playing field should do the best we can to allow people to compete.

Now, where are those costs going to go? I don't know if there will be any higher costs. I think what will probably wind up happening is PBMs are going to have people driving a harder bargain on behalf of whom? The consumer. The consumer is ultimately who these neighborhood pharmacies represent. When they go back and say, "I want a lower price for this drug" to the PBM and I've got, now, 50 of my buddies with me, rather than just little old me, what winds up happening? Now, does the PBM say, "Okay, we'll give you a $5 discount."

But that is what we are supposed to be trying to encourage here. There are a lot of deeply partisan issues about how you deal with health care. I think competition is the abiding thing that we all agree that, if we had, everyone would benefit from.

So the chain stores, they already have this. We're not asking—they're not going to lose a single right. If you are someone who is advocating on behalf of letting the chains stores prosper, so be it; they don't lose a single right. H.R. 971 doesn't not touch them one wit, unless you think that allowing a chain pharmacy to be able to better compete harms them. If you don't want competition, I don't think you should come here to the Judiciary Committee and say it.

So this is a case that we can do something that has no cost to the Government, has little administrative costs, if any, to the Government, because it will be individuals who are going to be able to negotiate. And it allows us to do something now, quickly and immediately, to try to save the one last remaining noncontroversial element of our national health care system, and that is the neighborhood community pharmacist who is there every single day, answering questions large and small, dealing with a much more complicated, complex world of pharmaceuticals than we've ever had before.

Before I yield back, think for a moment whether or not we would be better off or worse off if we continue this decline of community pharmacies closing. And I think you will realize, almost by any measure, we'd be worse off.

And I thank you, Mr. Chairman, for holding this hearing.

Mr. CONYERS. Well, I appreciate that analysis.

And I now turn to my friend from California, Darrell Issa, who has never been shy—I had to cross out some adjectives. "Shy," "retiring" and "unassuming" were never phrases used to describe the gentleman from California. And yet we recognize him now for 5 minutes.

Mr. ISSA. Well, thank you, Mr. Chairman. My wife often says "seldom mistaken, never in doubt," when describing me. Perhaps you could use that in the future. That sounds like a good one.

Mr. CONYERS. Would the gentleman——

Mr. ISSA. I would yield to the gentleman from Ohio.

Mr. CHABOT. I'll be very brief. I'm the Ranking Member of the Small Business Committee, and we have a markup at 10 o'clock. So we are definitely going to review the testimony of all the folks.

This is a very important issue. I want to thank the Chairman and the Ranking Member for holding this. Unfortunately a bunch of us have things at the same time.

So I want to thank the gentleman for yielding. I intend to come back. Thank you.

Mr. CONYERS. I support the notion that the gentleman from Ohio has been working on this issue for quite a long time.

And I thank the gentleman for allowing the interruption.

Mr. ISSA. Thank you, Chairman. And thank you for holding this important hearing.

I think, sometimes in these hearings, there is a preconception that we have already made our mind up. Nothing could be further from the truth, because the nature of legislation that rebalances antitrust is a delicate one. I think we all understand that somewhere between "antitrust" meaning no monopolies and "antitrust" meaning you can't talk to your wife about what is happening in her part of the business versus yours is where is the balance we want to achieve.

Having been a small-business man for many, many years in the electronics industry, I dealt with buying groups. I understand both, as a manufacturer, the negative that buying groups demand better, sharper prices, or, as they like to say, "sharpen your pencil." I also understand that you make one call, you negotiate one contract, and then you're able to sell in to a much larger network.

I think here today that we're balancing the fact that individual, family-owned and nonpublic drugstores are, in fact, inefficient to deal with. We, in fact, realize that to call on one store and negotiate one contract is, by definition, more expensive than going down to Walgreens or CVS or Wal-Mart, if you can get to Arkansas with a couple of flights, and negotiating contracts. So there's a tradeoff.

At the same time, we also understand that small businesses have been the innovators, small businesses have provided great service. And we want to make sure that they are allowed, under our antitrust law, to survive.

So, as we look at Mr. Weiner's legislation, either in whole or in part, or as is or with changes, I believe that what we're going to find is a lot of the testimony here today serves an understanding of why you can have a buyer's group to buy drugs; what you can't do is have a group that agreed to be under a common contract that is, in fact, perhaps less competitive, less sharpened-pencil than CVS or Walgreens, and yet better for the companies who negotiate one contract for perhaps 200 or 300 small businesses, where the tradeoff for them also is a common contract.

In preparation for this, I discovered that there is no question that large companies, such as Wal-Mart and CVS—all of whom I applaud their ability to deliver good products at a good price—they also start off with a comparative blank sheet of paper when negotiating these contracts. If, in fact, what you have is one store on the corner near my home, you were sent a contract which you will sign or you will not participate. That cannot be allowed to continue.

So when we're looking at balancing antitrust, Mr. Chairman, I believe what we're going to see is we're going to see that if you have 10 percent market share with Wal-Mart and 4 percent market share with another chain and 6 percent with another chain, that if, in fact, independents come together and have no greater market power than, let's say, either the average of the top three or certainly no greater than the greatest in an area, that, by definition, the rebalancing could do no harm to the intent of the antitrust laws, which is to ensure that there is competition.

The fact is that the independents today represent perhaps too much of small and not enough to compete against big. And I look forward to hearing it in detail. I look forward to working with Mr. Weiner and this Committee on legislation that really could provide a narrow but meaningful exemption.

And, with that, I yield back.

Mr. CONYERS. I thank the gentleman very much for his presentation.

Mr. Weiner and myself, right now, so far, we are the witnesses and you are the Committee. Because you've heard some fascinating analysis that could be the basis of a discussion on these views alone.

But now it's your turn. And what a wonderful set of five witnesses: Dr. Robert Dozier, attorney David Balto, David Wales, and Peter Rankin, and finally Mike James. What a great way to begin or, really, more accurately, continue this discussion that has been started.

And so, I want to begin with Mike James, the vice president of government relations at the Association of Community Pharmacists Congressional Network. He is an owner of independent pharmacies in North Carolina and Florida. He has chaired the North Carolina Retail Merchants Association and was named North Carolina pharmacist of the year.

We've got all your testimony; it will go into the record.

And we invite you to begin, sir.

TESTIMONY OF MIKE JAMES, VICE PRESIDENT, ASSOCIATION OF COMMUNITY PHARMACIES CONGRESSIONAL NETWORK, AND PHARMACIST/OWNER, PERSON STREET PHARMACY, RALEIGH, NC

Mr. JAMES. Thank you very much, Mr. Chairman——

Mr. CONYERS. Try to press the button again.

Mr. JAMES. Is it working now?

Mr. CONYERS. It doesn't seem to be working now. We've been having a lot of technical difficulties in this hearing room, and I apologize for that.

Mr. JAMES. How about this one?

Mr. CONYERS. Excellent.

Mr. JAMES. Chairman Conyers, Ranking Member Keller, Members of Antitrust Task Force, good morning. And thank you for allowing me to testify this morning on behalf of the Association of Community Pharmacy Congressional Network and the independent hometown pharmacies they represent across the country. I would also like to thank you for holding this hearing to address a crucial problem in the health care system.

My name is Mike James. I am vice president and director of government affairs for the Association of Community Pharmacy Congressional Network and a practicing pharmacist at an independent community pharmacy in Raleigh, North Carolina.

As managed care became the norm in the health care industry, pharmacy benefit managers began to realize they could become a bigger player in the business of health care. Their business model was to manage prescription programs and promise huge savings,

but these so-called savings came with a high price for consumers and pharmacies.

Today, about 95 percent of all prescriptions filled in the United States are handled by PBMs. As a result of this power, the PBM industry now dictates, without negotiation, reimbursement rates and terms of contracts to independent pharmacies. In order to continue serving your patients, pharmacies are required to fill prescriptions under PBM arrangements at prices that do not cover cost. This has resulted in the closing of 1,152 independent hometown pharmacies in 2006.

Every pharmacy owner I have spoken with who has closed indicated that their reason for closing was low third-party PBM reimbursements. The PBM strategy is working well, and I believe we will see a larger number of closings this year and next if nothing is done.

The takeover by PBMs is also resulting in movement on a large scale of senior patients to mail-order prescription programs. They have no say in how their pharmacy benefits will be delivered and are afraid to complain in fear of losing their benefit. These patients are denied their traditional right to seek personal and confidential professional assistance from local hometown pharmacy professionals.

Today the goal of PBM contracts is not to support critical pharmacy-patient relationship. Rather, the goal is to systematically undermine the solvency of independent pharmacies and force patients covered under these agreements into highly profitable proprietary mail-order programs. This is a conflict of interest. The PBMs run their own mail-order programs in direct competition with retail pharmacies. There is a distinct inequity by forcing patients to pay a higher co-pay in the pharmacy than they pay through mail-order. And it is putting patients at a disadvantage by not allowing a local retail pharmacy to fill a 90-day supply which is offered through mail-order.

You will be told that allowing negotiations will increase costs by $29 billion. This is strictly a decision of the PBM. PBMs have great flexibility in determining how much they shift over to patients and taxpayers.

CMS handed over all power and authority to PBMs to run Medicare Part D, but rather than be good stewards of the payers' interests, the $29 billion indicates that Charles River Associates and the Congressional Budget Office understand well that PBMs will continue to put their profits above the interest of the patient. If the cost goes up, it will be because the PBM raised cost, not because the pharmacies were allowed to negotiate.

You will also be told that surveys show a huge majority of Medicare Part D patients are happy with the program. I would contend this survey didn't include those patients who have entered no coverage zone or the donut hole, as it is called. I own a pharmacy, and I do surveys every day. And every day, I counsel patients who have hit the donut hole and have no idea how they're going to buy their medication.

The patient is paying a monthly premium; the Federal Government is paying a monthly allowance to the PBM. The patient is paying the total cost of the medication and is trapped in the donut

hole until the new year begins. All this time, the PBM is collecting money and paying nothing to help the patient receive their medication.

I can assure you, these patients are not happy with the program.

In many communities, pharmacies are the primary or only health care resource for American families. The human interaction with a patient is a vital part of the entire process of the delivery of care to the public. This is a fulcrum of the integration of standard of care for the patient.

Independent pharmacies must have the right to negotiate to keep these PBMs from taking over the prescription-delivery system, but antitrust law prohibits this right. With pharmacies closing every day and patients being forced into the mail-order program, I believe Congress must act. I believe Congress must give independent hometown pharmacies a way to help the patient, a way for pharmacies to negotiate a fair contract, and a way for these local pharmacies to continue to serve their communities and keep America healthy.

Mr. Chairman, this legislation is a cornerstone for the future of health care reform, because, without the independent pharmacy network, reform will not work. As you know, Mr. Chairman, this association, the Association of Community Pharmacy Congressional Network, has worked for months on this legislation. And I ask for you, the Committee, to move this legislation forward to markup to enable passage of this important bill.

Thank you for your time, Mr. Chairman. I appreciate the opportunity to speak with you.

[The prepared statement of Mr. James follows:]

PREPARED STATEMENT OF MIKE JAMES

Chairman Conyers, Ranking Members Smith and Keller, and Members of the Antitrust Taskforce, good morning and thank you for allowing me to testify this morning on behalf of the Association of Community Pharmacies Congressional Network and the independent pharmacies they represent across the country. I would also like to thank you for holding this hearing to address a crucial problem in the health care system.

My name is Mike James; I am Vice President and Director of Government Affairs for the Association of Community Pharmacies Congressional Network, a practicing pharmacist and the owner of an independent, community pharmacy in Raleigh, North Carolina.

Years ago, as managed care began to invade health care in this country, insurance companies began to hire Pharmacy Benefit Administrators (known as PBAs) to become electronic claims clearing houses between the insurance company and the pharmacies. This was done in an effort to centralize all claims from the thousands of pharmacies to a central switch, to then be routed to the correct insurance company. This is a transaction much like a credit card transaction—a central switch, an electronic transfer.

But as managed care became the norm, these PBAs began to realize they could become a bigger player in the *business* of health care and convinced insurance companies, large corporations, and government entities that they were the experts in the prescription delivery process. These PBAs sold this idea as a cost-savings mechanism. The Pharmacy Benefit Administrators then became known as Pharmacy Benefit Managers (PBMs) and their business model was to manage the entire prescription program and promised as much as 30 to 40% off prescription prices to the insurance companies. But these so-called "savings" came at a high price for consumers and pharmacies.

Back when the Pharmacy Benefit Administrators were used, they handled about 10% of the prescriptions filled in the US. By 2005, the number of prescriptions being handled by PBMs was over 60%. Today, after the implementation of Medicare Part D, about 95% of all prescriptions filled in the United States are handled by PBMs.

As a result of this near-monopolistic power, the PBM industry now dictates, without negotiation, reimbursement rates and terms of contracts to independent pharmacies. In order to continue serving their patients, pharmacies are required to fill prescriptions under PBM agreements at prices that do not cover costs. This has resulted in the closing of 1,152 independent pharmacies in 2006. Every one of the pharmacy owners I have spoken with who has closed their pharmacy since January 2006 indicated that their reason for closing is low third-party PBM reimbursement. The PBM strategy of putting independent pharmacy out of business is working well and I believe we will see a larger number of closings in 2007 and 2008 if nothing is done.

The take-over by PBMs is also resulting in movement on a large-scale of senior patients—particularly those in rural areas—to mail-order prescription programs. This has provided a perverse outcome for patients, who have no say in how their pharmacy benefits will be delivered, and are afraid to complain in fear of losing their benefit. These patients are denied their traditional right to seek personal and confidential professional assistance from local, hometown pharmacy professionals.

Today, the goal of PBM contracts is not to support critical pharmacy-patient relationships. Rather, the goal of PBM contracts is to systematically undermine the solvency of independent pharmacies and force patients covered under the agreements into highly profitable proprietary mail-order programs. PBMs promote mail-order as a cheaper alternative to visiting your local pharmacy. However, this is a conflict of interest—the PBMs run their own mail-order programs in direct competition with retail pharmacies. The argument of cost-savings is completely false—mail order programs won't necessarily offer a less expensive generic alternative to a medication because the PBM has rebate agreements with the brand drug makers. And the mail-order programs can't possibly fill a script the day it is written—there must still be a local pharmacy to fill that script written for antibiotics to cure an infection or a painkiller after a broken bone is set. Can those patients mail off the prescription and wait another two weeks before it arrives in the mail?

The mail-order programs run by PBMs are truly a conflict of interest. For example, there is a distinct inequity of forcing patients to pay a higher co-pay in the pharmacy for the same prescription than they pay through mail-order. And it is putting patients at a disadvantage by not allowing a local retail pharmacy to fill a 90-day supply when that same benefit is offered through mail-order. But the PBMs do this because they run the mail-order programs and these are effective methods of putting retail pharmacy out of business.

You will be told that allowing negotiation will increase cost by $29 billion dollars. This is strictly a decision of the PBM. PBMs have great flexibility in determining how much they shift over to patients and taxpayers. CMS handed over all power and authority to PBMs to run Medicare Part D, but rather than be good stewards of the taxpayers' interest, the $29 billion indicates that Charles River Associates and the Congressional Budget Office understand well that PBMs will continue to put their profits above the interest of the taxpayer. If the cost goes up, it will be because the PBMs raised cost, not because the pharmacies were allowed to negotiate.

You will also be told that surveys show a huge majority of Medicare Part D patients are happy with the program. I would contend this survey didn't include those patients who had entered the "no coverage zone" or "doughnut hole" as it is called. I own a pharmacy and I do surveys everyday and everyday I council patients who have hit the doughnut hole and have no idea how they are going to buy their medication. They are still paying a monthly premium, the Federal government is still paying their monthly allowance to the PMB for that patient and the patient is paying the total cost of the medication and will not escape the doughnut hole before the program begins again in January. All this time, the PBM is collecting money and paying nothing to help the patient receive their medication. I can assure you these patients are not happy with the program.

Independent pharmacies provide invaluable health care services on a daily basis to millions of patients nationwide. They know their patients and their health care history. This is especially important for patients who have multiple doctors and prescriptions. The pharmacist is the only health care professional who knows all of the patient's medications, their interactions, and whether there are lower cost generics available to address the patient's needs.

Hometown pharmacies are the only health care providers who do not require appointments and in many communities, pharmacists are the primary or only health care resource for American families. The role of the hometown pharmacist as part of the health care team cannot be duplicated through the PBM mail-order process. The human interaction with the patient is a vital part of the entire process of the delivery of care to the public—this is the fulcrum of the integration of standard of

care for the patient. Patients can't ask their postman about their medication—not everyone can call a 1-800 number and navigate through a directory of options only to be put on hold or speak with an operator nor will everyone remember to order each of their prescriptions two weeks before they run out—many patients take multiple drugs, especially seniors and those who have serious illnesses. Shouldn't we be taking extra care with them rather than forcing them into faceless mail-order programs?

There is only one way to combat the takeover of your constituents' health care by these huge companies whose only interest is the bottom line, not the health of patients. Independent pharmacies must have the right to negotiate to keep these PBMs from taking over the prescription delivery system. But antitrust law prohibits these small pharmacies from banding together to discuss terms of a contract. If Main Street Pharmacy talks to Elm Street Pharmacy about reimbursement rates or dispensing fees and agree to turn down the contract from a PBM unless they offer a reasonable contract, they are in violation of the law. Currently, these pharmacies tend to accept contracts that will put them at a loss because they lead with their hearts, not with their business sense. But with pharmacies shutting down every day, and the alternative being patients forced into mail order or going to the next town to get their prescription filled, I believe Congress must act. When Medicare Part D was signed into law, PBMs were given more power, more lives to control—now almost every American with prescription drug coverage is at the mercy of a PBM. I believe Congress must give independent pharmacies the right to negotiate, a way to help the patient, a way for pharmacies to negotiate a fair contract, a way for these local, hometown pharmacies to continue to serve their communities and keep America healthy.

Mr. Chairman, this legislation is the cornerstone for the future of healthcare reform because without the independent pharmacy network, reform will not work. I ask you and this committee to move this legislation forward to mark-up to enable passage of this important bill.

Thank you for this time.

Mr. CONYERS. Thank you, Mr. James. It has been a long time before you could get before the Committee to lay this problem out from your perspective and experience. I am so glad that we have your full statement to go through the position that you've outlined.

We now turn to the senior associate at Charles River Associates, Peter Rankin. Dr. Rankin earned his Ph.D. In economics at Duke University. He's become a leading researcher in health care and pharmaceutical industries. His most recent research is focused on the influence of Medicare and managed care on the marketplace.

I apologize for not having looked those articles up, so I don't know what you said, but they certainly are important and are not unrelated to what brings us here this morning.

Welcome, Dr. Rankin.

TESTIMONY OF PETER J. RANKIN, PRINCIPAL, CRA INTERNATIONAL

Mr. RANKIN. Thank you. Good morning, Chairman Conyers, Ranking Member Keller and Members of the Task Force. My name is Peter Rankin. I am a principal at CRA International, formerly known as Charles River Associates, an economics and management consulting firm.

I testify today to raise concerns regarding the economic and potential unintended consequences of H.R. 971. The proposed legislation would provide antitrust exemptions to pharmacies not owned or operated by a publicly traded company. Supporters of this bill believe that these independent pharmacies need an antitrust exemption because they are at a competitive disadvantage in negotiating contracts with health insurers or pharmacy benefit managers.

My analysis and research leads me to conclude that such a drastic policy change is not warranted. And I will focus on three points.

First, patients and payers, including Medicare, would bear the burden of higher costs. A conservative estimate is that the bill would increase expenditures by nearly $30 billion over 5 years, nearly a quarter of which would be higher spending on Medicare Part D.

Second, antitrust waivers for independent pharmacies are not warranted.

Third, in general, antitrust waivers are inefficient and threaten to raise additional competitive concerns.

I would like to submit for the record in my written testimony CRA's report on this legislation.

Mr. CONYERS. Without objection, so ordered.

Mr. RANKIN. The first concern: Antitrust waivers are expensive. Antitrust waivers would allow independent pharmacies to collude on pricing and services in negotiations with health insurers and PBMs. Considering only the direct cost effects of increases and charges, independent pharmacy waivers will increase spending by up to $29.6 billion over 5 years, or an increase of up to 11.8 percent, with nearly one-quarter of that amount accruing to Medicare Part D plans.

These costs are likely to be ultimately passed on to Medicare, health insurers, employers and patients. As costs increase, patients fill fewer prescriptions, and employers will likely scale back, reduce or even eliminate health care coverage for their employees. Including consideration of reduced or eliminated access to health care, the total costs of independent-pharmacy antitrust exemptions exceed the financial costs estimated by the CRA report.

The second concern: Antitrust waivers for independent pharmacies are not warranted. There are examples of independent pharmacies with economic difficulties. However, antitrust laws are not designed to protect individual pharmacies that may be harmed by competition, but rather to insure that consumer welfare is maintained with access to pharmacies with reasonable prices and quality. Current antitrust laws provide legitimate mechanisms for pharmacies to negotiate with PBMs when such collaboration enhances the quality or efficiency of care to patients. And independent pharmacies already have organizations that can collectively represent their interests.

The third concern: Antitrust waivers are not effective. The Federal Trade Commission and Department of Justice actively enforce the antitrust laws in the health care industry. The regulatory agencies and most economists have regularly dismissed the concept of combating perceived competitive imbalances in market power by creating countervailing market power. The appropriate response, instead, is to determine if there is a legitimate competitive imbalance and to address the economic factors creating that imbalance directly.

Antitrust waivers legalize collusive behavior to create market power. Relying on waivers to address perceived competitive imbalances requires continuous adjustment and interference in economic markets and runs the risk of spreading competitive imbalance to

related markets as the protected entities engage in other lines of business.

In conclusion, antitrust exemptions are drastic and expensive tools to address a perceived competitive imbalance between independent pharmacies and PBMs. My analysis leads me to conclude that no such competitive imbalance exists in this area. To the extent that prices paid to pharmacies have been reduced, these price reductions have benefited consumers. Antitrust exemptions amount to a wealth transfer from payers and patients to independent pharmacies of up to $29.6 billion over 5 years.

I thank you for the opportunity to share some of these concerns that I have with H.R. 971. Thank you.

[The prepared statement of Mr. Rankin follows:]

PREPARED STATEMENT OF PETER J. RANKIN

Testimony of Peter J. Rankin, Ph. D.

Principal

CRA International

Before the

UNITED STATES HOUSE OF REPRESENTATIVES
JUDICIARY COMMITTEE
ANTITRUST TASK FORCE

Hearing on the Impact of our Antitrust Laws on
Community Pharmacies and their Patients

October 18, 2007

Good morning Chairman Conyers, Ranking Member Keller, and Members of the Task Force. My name is Peter Rankin. I'm a Principal at CRA International, an economics and management consulting firm.

I testify today to raise concerns regarding the economic and unintended consequences of H.R. 971. The proposed legislation would provide antitrust exemptions to pharmacies not owned or operated by a publicly traded company. Supporters of this bill believe that independent pharmacies need an antitrust exemption because they are at a competitive disadvantage in negotiating contracts.

My analysis and research leads me to conclude that such a drastic policy change is not warranted and I will focus on three points:

- First: Patients and payors, including Medicare, would bear the burden of higher costs. A conservative estimate is that the bill would increase expenditures by nearly $30 billion over five years, nearly a quarter of which would be higher federal spending on Medicare Part D.

- Second: Antitrust waivers for independent pharmacies are not warranted.

- Third: In general, antitrust waivers are inefficient and threaten to raise additional competitive concerns.

I would like to submit for the record in my written testimony CRA's report on this legislation.

I. Antitrust waivers are expensive

Antitrust waivers would allow independent pharmacies to collude on pricing and services in negotiations with health insurers and PBMs. Considering only the direct cost effects of increases in charges, independent pharmacy waivers will increase spending by up to $29.6 billion over five years (or an increase of up to 11.8 percent), with nearly one-quarter of that amount accruing to Medicare Part D plans.

These costs are likely to be ultimately passed on to Medicare, health insurers, employers, and patients. As costs increase, patients fill fewer prescriptions and employers will likely scale back, reduce, or even eliminate health care coverage for their

employees. Including consideration of reduced or eliminated access to health care, the total costs of independent pharmacy antitrust exemptions exceed the financial costs estimated by the CRA report.

2. Antitrust waivers for independent pharmacies are not warranted.

There are examples of independent pharmacies with economic difficulties. However, antitrust laws are not designed to protect individual pharmacies that may be harmed by competition, but rather to insure that consumer welfare is maintained through access to pharmacies with reasonable prices and quality. Current antitrust laws provide legitimate mechanisms for pharmacies to negotiate with PBMs, when such collaboration enhances the quality or efficiency of care to patients, and independent pharmacies already have organizations that can collectively represent their interests.

3. Antitrust waivers are not effective

The Federal Trade Commission and Department of Justice actively enforce the antitrust laws in the health care industry. The regulatory agencies and most economists have regularly dismissed

the concept of combating perceived competitive imbalances in market power by creating "countervailing" market power. The appropriate response, instead, is to determine if there is a legitimate competitive imbalance and address the economic factors creating that imbalance.

Antitrust waivers legalize collusive behavior to create market power. Relying on waivers to address perceived competitive imbalances requires continuous adjustment and interference in economic markets and runs the risk of spreading competitive imbalance to related markets as the protected entities engage in other lines of business.

Conclusion

Antitrust exemptions are drastic and expensive tools to address a perceived competitive imbalance between independent pharmacies and PBMs. My analysis leads me to conclude that no such competitive imbalance exists in this area. To the extent that prices paid to pharmacies have been reduced, these price reductions have benefited consumers. Antitrust exemptions amount to a wealth transfer from payors and patients to independent pharmacies of up to $29.6 billion over five years.

ATTACHMENT

1. INTRODUCTION

In 2005, Representatives Anthony Weiner (D–NY) and Jerry Moran (R–KS) co-sponsored H.R. 1671 as part of an effort to secure antitrust exemptions for independent pharmacies that would allow them to negotiate collectively with PBMs and health plans.[5] While the legislation did not pass in 2006, the legislation was reintroduced in 2007 as H.R. 971. The proposed antitrust exemptions for independent pharmacies are not the first attempted in the health care industry; previous proposed legislation would have provided physicians and pharmacists with antitrust exemptions.[6] The national provision of physician and pharmacist antitrust exemptions would have increased the costs of healthcare by 0.9 to 2.7 percent as a result of direct price increases and indirect costs associated with resulting changes in utilization of health care services ordered by physicians.[7]

This study evaluates one of the cost increases that would likely result from granting antitrust exemptions to independent pharmacies,[8] namely the magnitude of price increases that would occur with collective negotiation by independent pharmacies on reimbursement terms. (It does not consider a number of other policy changes that might result from granting antitrust exemptions, which have been studied in other contexts).[9] In particular, this study finds the following:

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5 As defined by H.R. 971, an independent pharmacy is defined as a pharmacy that is not owned or operated by a publicly traded company. As noted by the John Rector, the Senior Vice President for Government Affairs and General Counsel for the National Community Pharmacists Association ("NCPA"), the definition used by H.R. 1671 "will help us avoid the problems associated with the wrong-headed definition used by IMS, the National Association of Boards of Pharmacy, and others misrepresenting the marketplace by designating the owner of four or more pharmacies as a chain, not as an independent." (See http://www.ncpanet.org/pdf/amrx_200506_notes.pdf, accessed April 18, 2006). The National Association of Chain Drug Stores ("NACDS"), alternatively, defines independent pharmacies as those with three or fewer locations. See 2005 NACDS Profile, p. 10. For the purposes of clarity, this study uses the definition provided by H.R. 971.

6 See, for example, the Quality Health Care Coalition Act, H.R. 1304, introduced in March 1999. At least one supporter of the independent pharmacy exemption legislation, the American Pharmacy Cooperative, Inc. ("APCI"), characterized H.R. 1671 as "similar to H.R. 1304" (See APCI "Call to Action").

7 *The National Costs of Physician Antitrust Waivers*, prepared for Health Insurance Association of America (now America's Health Insurance Plans, or AHIP), Charles River Associates Inc., March 2000, p. 6.

8 As written, H.R. 971 excludes from the exemption program negotiations with Federal programs (e.g., Medicaid, Federal employee health benefit program ("FEHBP")). The cost estimates of this study assume costs would accrue only from commercial insurance accounts (i.e., Medicaid and cash prescription transactions are excluded from consideration).

9 Other reports have considered the cost implications of other types of behavior that might result from independent pharmacies antitrust exemptions. See, for example, PricewaterhouseCoopers, "Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost Impact of Proposed PBM Legislation, 2008-2017," pp. 2, 16, which found that requiring PBMs to publicly disclose details on negotiated discounts would increase drug costs to Medicare and private payers by $219 billion over the 2008-2017 period.

- Current antitrust laws provide legitimate mechanisms for pharmacies to collaborate to negotiate with payers and PBMs, when such collaboration enhances the quality or efficiency of care to patients;

- Under proposed pharmacy antitrust exemption legislation, direct costs to payers could increase by up to $29.6 billion over 5 years, an increase of 11.8 percent of total prescription sales across all independent pharmacies;[10]

- More than $6.4 billion of the increased costs over 5 years would be attributable to implementation of Medicare Part D; and

- Cost increases from the proposed legislation would be passed through to health insurers and employers, providing pressure to increase costs and/or reduce health insurance coverage for employees and patients.

Each of these findings is discussed in greater detail below. Section 2 describes the distribution of and reimbursement for pharmaceutical prescriptions. Section 3 considers the economic support for antitrust exemptions and includes a discussion of the current mechanisms to protect competition. Section 4 summarizes literature and opinions regarding the distribution of cost increases that would result from granting antitrust exemptions. Section 5 provides estimates that antitrust exemptions to independent pharmacies would increase costs by up to $29.6 billion over five years, or 11.8 percent of total prescription sales across independent pharmacies.

2. CURRENT PBM PRACTICES REDUCE COSTS WHILE LEAVING INDEPENDENT PHARMACIES PROFITABLE

The number of prescriptions dispensed has increased substantially over the past ten years.[11] Insurance coverage of pharmaceuticals began when most health insurance plans operated on an indemnity, or fee-for-service ("FFS") basis. Under FFS insurance, patients typically had to make a coinsurance payment for prescriptions, often 20 percent of the negotiated price. The pharmacy at which a patient filled a prescription sometimes had arrangements with health insurers for discounts, but the patient often bore the responsibility of paying the full price of the prescription and seeking reimbursement from the health insurer. Consumers without insurance coverage typically paid undiscounted, full retail prices at the pharmacy counter.

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10 The details of this analysis are addressed below.

11 See, for example, *Prescription Drug Trends*, The Kaiser Family Foundation, November 2005, p. 1. The 2006 NCPA-Pfizer Digest reported a 2.8 percent increase in prescription volume between 2004 and 2005. See 2006 NCPA Digest, p. 6.

2.1. Payers Rely on Networks and Other PBM Cost Control Techniques to Limit Prescription Expenditures

More comprehensive managed benefit plans rapidly replaced the FFS private health insurance model in the 1990s, shifting the source of payment for prescriptions from patients to their insurers. In 1980, patient out-of-pocket spending accounted for 70 percent of prescription expenditures. By 2004, patients' out-of-pocket payments had fallen to 25 percent of spending on prescription drugs.[12] The increased numbers of consumers with prescription drug coverage had at least two significant effects on retail pharmacies. First, health plans sought to help employers and other plan sponsors to manage costs by establishing networks of health providers. Health plans (or their PBMs) also pooled the volume purchasing ability of the many consumers whose benefits they managed in order to negotiate favorable rates from health care providers (including pharmacies).[13] Second, communications between health insurers (or their PBMs) and healthcare providers often resulted in contracts that defined the reimbursement terms and duration of the agreement.[14] The reimbursement terms typically had two components: an "ingredient cost" and a "dispensing fee." In addition to this reimbursement, pharmacies also collected copayments, or flat per-prescription payments, from patients with health insurance that included prescription drug coverage.

The PBM business model has also evolved as management of the drug benefit has increased. From companies that initially handled only the administrative details of health insurance transactions, PBMs grew into sophisticated, integrated components of healthcare distribution and reimbursement. PBMs enter into contracts with "plan sponsors" – typically health insurers[15] or self-insured employers – to provide management of pharmacy benefit

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12 Centers for Medicare and Medicaid Services ("CMS"), *Historical National Health Expenditures (NHE) Amounts by Type of Expenditure and Source of Funds: Calendar Years 1965-2015.*

13 "By forming an exclusive network, a PBM is able to guide a covered entity's participants to certain pharmacies. The promise of increased customer volume creates an incentive for pharmacies to bid aggressively with lower drug prices in exchange for membership in a network. Pharmacies will be willing to compete more vigorously for inclusion in a network as the exclusivity of the network and the number of pharmacies in the relevant market increases." *March 8, 2005 Letter to Senator Richard L. Brown, North Dakota Senate*, Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics.

14 Some healthcare providers, including pharmacies, have claimed that there is no "negotiation" with the health insurer (or PBM). See, for example, John Rector, "Progress Steady on Community Rx Fairness Act," *America's Pharmacist*, August 2005, p. 56. Such a scenario does not by itself provide evidence of market power by an insurer or PBM (the criteria by which market power is defined are considered below). A scenario of little or no negotiation is at least as likely to demonstrate the competitiveness or oversupply of pharmacies. The terms of the contract would certainly change if a sufficient number of pharmacies opted not to accept the contracts.

15 In addition to commercial health insurers, government payers act as plan sponsors by contracting with PBMs to provide health care management for their own employees (e.g., FEHBP) and for the beneficiaries of government programs such as Medicare.

services. In general, PBMs handle claims processing, pharmacy network formation,[16] formulary creation and maintenance, manufacturer rebate negotiations, disease management, and the creation and implementation of additional programs to control drug costs (such as generic substitution or mail-order dispensing).[17] The degree to which a PBM accepts risk for cost overruns or trends depends on its contract with a plan sponsor, as do a number of other terms, such as whether and to what degree other PBM revenue (such as rebates) will be shared, the duration of the contract, and the penalties assessed for noncompliance with contract terms.[18]

2.2. PBMs Provide Substantial Cost Savings

Empirical evidence suggests that consumers with prescription drug insurance administered by a PBM save substantially on their drug costs as compared to cash-paying customers.[19] A study across 14 brand name drugs and 4 generics showed that health plan sponsors and their enrollees enjoyed prices that were 47 percent lower for generic drugs and 18 percent lower for brand name drugs.[20] Other commentators have noted that:

> Since PBMs reflect aggregate purchases representing all individuals within a drug coverage program, their reimbursement formulas are established to extract volume purchase discounts from pharmacies. Levels of prices paid by PBMs generally are the lowest or some of the lowest accepted by pharmacies for any types of customers. Prices paid by cash paying customers and even Medicaid programs in many states are higher than what a PBM would pay. Thus the PBM pricing approach can be

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16 In the current healthcare system, patients can obtain prescription drugs through a variety of different venues that include hospitals, physicians' offices, clinics, long-term care facilities, mail-service pharmacies, and several types of retail establishments, including chain drug stores, independent drug stores, mass merchants, and supermarkets.

17 *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, Federal Trade Commission, August 2005 ("FTC Mail Order Study 2005"), pp. 5-7, 10. The exact services provided by PBMs vary substantially depending on the needs and preferences of plan sponsors.

18 PBMs typically employ several methods that generate additional revenue. For example, formularies – lists of drugs that are reimbursed at certain levels – are common tools that reduce total costs by generating competition between branded pharmaceutical manufacturers to lower the effective net price of preferred drugs for patients and plan sponsors.

19 See *Improving Health Care: A Dose of Competition*, A Report by the Federal Trade Commission and the Department of Justice, Chapter 7, p. 16, July 2004.

20 See *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, General Accounting Office, 2003, accessed at http://www.gao.gov/cgi-bin/getrpt?GAO-03-196, which is quoted in *Improving Health Care: A Dose of Competition*, A Report by the Federal Trade Commission and the Department of Justice, Chapter 7, p. 11, July 2004.

> considered a negotiated price, volume discount strategy targeted at pharmacy providers.[21]

The Congressional Budge Office ("CBO") has noted that the degree to which PBMs can effectively control drug costs depends on "their being allowed and encouraged to aggressively use the various tools at their disposal."[22] According to CBO, these tools include, among others, forming limited pharmacy networks.[23] In estimating the extent to which PBMs could manage costs in Medicare, CBO estimated that PBMs could save as much as 30 percent over unmanaged costs if allowed and encouraged to use the full range of tools at their disposal.[24]

2.3. Independent Pharmacies Remain Profitable

Despite independent pharmacies' claims that their negotiations with PBMs do not occur on a "level playing field,"[25] independent pharmacies remain profitable. In 2005, the average gross profit margin that independent pharmacies earned on sales to commercial insurers (including Medicare managed care plans) was 19.3 percent, up 1.5 percentage points from the previous year. Their average gross profit margin on prescriptions filled for Medicaid beneficiaries in 2005 was 20.8 percent.[26] Their overall gross profit margin on prescriptions increased from 21.2 percent in 2004 to 22.7 percent in 2005, which coincided with an increase in volume.[27]

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21 See *Cost Control for Prescription Drug Programs: Pharmacy Benefit Manager PBM Efforts, Effects, and Implications.* Prepared for the Department of Health and Human Services' Conference on Pharmaceutical Pricing Practices, Utilization and costs, By Kreling, David, August 8-9, 2000. pdf p. 2. Similarly, the Federal Trade Commission found that "Retail pharmacies may compete over the discounts from the reference price (AWP or MAC) they will offer a PBM depending on the type of plan sponsors and the number of members covered by the PBM. Retail pharmacies generally will offer higher discounts to be in a more exclusive network, because each retail pharmacy will fill a larger percentage of prescriptions if fewer retail pharmacies are in the PBM's network. A PBM may have several networks, which differ in their exclusivity, that it offers its clients." FTC Mail Order Study 2005, p. 5.

22 See Congressional Budget Office, "Issues in Designing a Prescription Drug Benefit for Medicare," October, 2002, ("CBO 2002"), page xiii, accessed at http://www.cbo.gov/showdoc.cfm?index=3960&sequence=0.

23 CBO 2002, p. xiii. Other tools include formularies, disease-management programs, and efforts to educate patients and physicians. "All of those tools, to one degree or another, work by influencing physicians' or consumers' choices about what drug to prescribe or where to fill a prescription."

24 CBO 2002, p. 40.

25 "This legislation [H.R. 1671] would allow community pharmacies to negotiate on a more level placing field, helping to preserve these trusted elements of our communities." John Rector, Senior Vice President for Government Affairs for NCPA, *America's Pharmacist*, June 2005, p. 52. Accessed at http://www.ncpanet.org/pdf/amrx_200506_notes.pdf.

26 2006 NCPA Digest, p. 53.

27 2006 NCPA Digest, p. 11.

Additionally, in 2003 the number of independent pharmacies increased by over 400, which would have been unlikely to occur had the market for their services not been profitable.[28]

As privately-held institutions, independent pharmacies must provide owners with compensation as well as the normal economic profits expected to derive from a viable business entity. That is, the total net profit of an independent pharmacy, known as the "owner's discretionary profit," has two components: the owner's compensation and the net profit to the pharmacy. In 2005, average payroll expense including owner compensation increased by 1.2 percent of sales.[29]

According to a firm that facilitates the sales of independent community pharmacies, the owner's compensation component of profit is attractive: "Despite the intense pressure on prescription department profit margins, the more than 20,000 independent owners in this country continue to earn a substantial living, one which…places these owners in the top 4% of all United States wage earners."[30] Indeed, it appears that factors outside of financial performance, including buyouts from chain pharmacies as well as a nationwide shortage of new pharmacists, might be responsible when an independent pharmacy business elects to close.[31]

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28 See *Gross Margins, Net Profits Up for Independents*, Drug Store News, No. 9, Vol. 26, July 19, 2004, p. 30.

29 2006 NCPA Digest, p. 10.

30 "Owning an Independent Pharmacy," Buy-Sell A Pharmacy.Com, 2005, accessed at, http://www.buy-sellapharmacy.com/Article%20OWNING%20AN%20INDEPENDENT%20PHARMACY% 20062404.pdf. Buy-Sell A Pharmacy.Com has a partnership with NCPA. See *NCPA Seeks New Independent Pharmacy Owners*, Drug Topics, No. 22, Vol. 147, November 17, 2003, p. 33.

31 "Recently…access to pharmacy services in rural areas has begun to receive more attention, as a result of … pharmacist shortages in some rural areas." Casey, M., Klingner, J., and Moscovice, I. *Access to Rural Pharmacy Services: Is the Problem Geographic Access or Financial Access?* Journal of Rural Health 18: 467-476, 2002. p. 1. (Note, however, that this study was not designed to address pharmacist supply issues). Similarly, "Finding relief pharmacists to fill in for those who are sick or on vacation is 'one of the biggest problems facing rural community practices - and small rural hospitals for that matter.'" *Special Delivery*? Innovations are Changing How, Where and When People Receive Pharmacy Services - Not Everyone Is Thrilled, Ronald A Wirtz, FedGazette, January 2006 ("Wirtz 2006a"), p. 7.

3. ANTITRUST EXEMPTIONS FOR HEALTH CARE PROVIDERS ARE UNNECESSARY

3.1. CURRENT ANTITRUST REGULATION AND ENFORCEMENT SAFEGUARDS COMPETITION

The Federal Trade Commission ("FTC") was created in 1914 to "prevent unfair methods of competition in commerce."[32] The charge of the Antitrust Division of the U.S. Department of Justice ("DOJ"), similarly, has been to "promote and protect the competitive process – and the America economy – through the enforcement of the antitrust laws."[33] Together, and supplemented by State Attorneys General, these agencies monitor competition and enforce laws and regulations intended to protect consumers from inappropriate corporate behavior. Of primary concern is the concept of "market power," often described as the ability for sellers profitably to inflate prices charged or for buyers to suppress prices paid, relative to competitive levels, for a significant period of time. The regulatory agencies monitor both areas where sellers appear to be increasing prices above competitive levels (e.g., monopoly) as well as circumstances where purchasers appear to be decreasing prices below competitive levels (e.g., monopsony).

In order to enforce antitrust and protect competition, the regulatory agencies have established a series of general, and in some cases industry-specific, guidelines to distinguish appropriate and problematic corporate behavior. For example, the FTC and DOJ jointly issued and regularly update the Horizontal Merger Guidelines guidance, which identify the types of behaviors and market conditions likely to violate competition laws.[34]

3.2. THERE IS NO RATIONALE FOR ANTITRUST EXEMPTIONS TO "LEVEL THE PLAYING FIELD"

Contentions that antitrust exemptions are needed presuppose some market imbalance that cannot be addressed by current competition laws and regulatory authorities. Antitrust exemptions, by definition, allow the legal formation of an economic entity that can create and maintain market power through coordinated behavior. Regulatory agencies and most economists have regularly dismissed the concept of combating perceived market power by creating "countervailing" market power. Such attempts are inefficient, requiring continued adjustment and interference in economic markets while running the risk of spreading competitive imbalance to related markets as the protected entities engage in various lines of business.

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32 See http://www.ftc.gov/bcp/conline/pubs/general/guidetoftc.htm.

33 See http://www.usdoj.gov/atr/overview.html.

34 *Horizontal Merger Guidelines*, U.S. Department of Justice and the Federal Trade Commission, Issued April 2, 1992; Revised April 8, 1997. Accessed at http://www.usdoj.gov/atr/public/guidelines/horiz_book/hmg1.html.

The FTC and DOJ have been particularly active in their enforcement of the antitrust laws in the health care industry through both prosecutorial activities and analysis and study. They have also provided substantial guidance to the health care industry through their Health Policy Statements,[35] and through various business review letters and advisory opinions on specific topics. In recent years, they have focused extensively on the health care industry in hearings and analysis. The agencies held an extensive set of hearings on health care competition, which resulted in the publication of a thorough evaluation of the state of competition in health care, entitled "Improving Health Care: A Dose of Competition" in July 2004. The FTC also undertook an analysis of mail order pharmacy services, which encompassed a review of the state of competition among PBMs in general.[36]

In general, the federal antitrust agencies have supported the maintenance of competition by letting markets function when possible and intervening when they discern market power. In the particular context of antitrust exemptions, while chairman of the FTC, Robert Pitofsky noted: "From a policy and enforcement perspective, the most effective response to the emergence of excessive buyer power is not to permit the aggregation of some form of countervailing power. Rather, the appropriate response is to try to prevent the aggregation of excessive buying power in the first place."[37] As noted in the FTC/DOJ "Dose of Competition" report, "The Agencies believe that antitrust enforcement to prevent the unlawful acquisition or exercise of monopsony power by insurers is a better solution than allowing providers to exercise countervailing power. Joel Klein, the Assistant Attorney General in 1999, noted that a 'better approach [than allowing countervailing market power] is to empower consumers by encouraging price competition, opening the flow of accurate, meaningful information to consumers, and ensuring effective antitrust enforcement both with regard to buyers (health care insurance plans) and sellers (health care professionals) of provider services.'"[38]

As a result, the agencies have monitored consolidation among health insurers and PBMs and have taken action where they have felt it necessary. For example, in 2005 the DOJ investigated UnitedHealthcare's acquisition of PacifiCare. Before allowing UnitedHealthcare to proceed with the transaction, the DOJ required it to divest pieces of the combined entity in Tucson, Arizona and Boulder, Colorado in order to prevent what it perceived as the potential for the exercise of market power in the purchase of physician services in these areas.[39]

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35 Revised Federal Trade Commission Justice Department Policy Statements on Health Care Antitrust Enforcement, issued 8/26/96, available at http://www.ftc.gov/reports/hlth3s.htm.

36 Dose of Competition. See also *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, Federal Trade Commission, August 2005.

37 *Level Playing Fields in Health Care Markets*, speech delivered by FTC Chairman Robert Pitofsky to the National Health Lawyers Association, February 13, 1997.

38 Dose of Competition, Chapter 2, p. 21. Parenthetical material included in source material.

39 Competitive Impact Statement, United States of America v. UnitedHealth Group Inc., and PacifiCare Health Systems, Inc., United States District Court for the District of Columbia, Judge Ricardo M. Urbina, March 3, 2006, accessed at http://www.usdoj.gov/atr/cases/f215000/215034.htm.

Similarly, the FTC has reviewed several mergers in the PBM industry, and only allowed them to proceed after it was sure that competition would be maintained.[40] For example, it concluded its investigation of Caremark Rx, Inc.'s proposed acquisition of AdvancePCS with the following statement:

> We also considered whether the proposed acquisition would confer monopsony (or oligopsony) power on PBMs when they negotiate dispensing fees with retail pharmacies....In the present case, there is no reason to expect a monopsony or oligopsony outcome – i.e. one in which the overall purchases from pharmacies are reduced – even if the acquisition enables the merged PBM (or PBMs as a group) to reduce the dispensing fees they pay to retail pharmacies. Characteristics of the relevant market make monopsony or oligopsony power unlikely. For example, contracts are individually negotiated between each PBM and each retail pharmacy company. In any event, the post-acquisition share of the merged firm for all purchases of prescription dispensing services would be below the level at which an exercise of monopsony power is likely to be profitable.[41]

As noted earlier, the FTC also undertook a thorough review of the PBM industry in its study of mail order pharmacies and concluded that "[d]ata in the report demonstrate that PBMs' use of owned mail-order pharmacies generally is cost-effective for plan sponsors."[42] The FTC has also found that the PBM industry is competitive and that restrictions on its behavior, such as requiring "transparency" or restricting its ability to contract selectively, would hinder, rather than abet, the competitive process, resulting in higher costs.[43]

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40 For example, the FTC recently cleared the merger of CVS (retail pharmacy) and Caremark (PBM), and considered the competitive implications of a proposed merger between PBMs Caremark and Express Scripts. Rose, French, "Express Scripts Seeks More Time for FTC Review of Caremark Bid", *Associated Press State & Local Wire*, January 31, 2007.

41 Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./Advance PCS*, File No. 031 0239, February 11, 2004, accessed at http://www.ftc.gov/os/caselist/0310239/0310239.htm. (Footnotes omitted.)

42 FTC Chairman Deborah Platt Majoras, quoted in *FTC Issues Report on PBM Ownership of Mail-Order Pharmacies*, September 6, 2005.

43 For example, the FTC evaluated proposed legislation in California (A.B. 1960) that would have required increased disclosure of certain financial information by PBMs. The FTC noted that the proposed legislation was likely to increase prices and costs of pharmaceuticals, and concluded that "vigorous competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms." (http://www.ftc.gov/opa/2004/09/capbm.htm, accessed October 5, 2004). Similarly, the FTC evaluated proposed legislation in North Dakota that would limit PBMs' abilities to engage in selective contracting. The FTC noted that the proposed legislation (H.B. 1332) would "prevent covered entities from designing benefit plans to encourage participants to use network pharmacies that provide drugs to the plan at a lower cost than other network pharmacies." *March 8, 2005 Letter to Senator Richard L. Brown, North Dakota Senate*, Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics.

In general, the FTC has found other practices used by MCOs that might be thought to restrict competition, such as contracting with a limited set of providers ("selective contracting"), to be pro-competitive in many situations, as it explained in its comments to Rhode Island officials regarding seven pieces of proposed legislations intended to preserve "freedom of choice" for patients requiring pharmacy services and to allow "any willing provider" to join pharmacy networks:

> Competition among third party payers and health care providers can enhance the range of services available to consumers and reduce health care costs. The Commission has noted that the use of limited panels of health care providers has been an effective means of promoting competition and lowering the price of health care services. The Commission has accordingly taken law enforcement action against anticompetitive efforts to suppress or eliminate health care programs that use selective contracting to create a limited panel of health care providers. FTC staff has also submitted comments to government bodies about the competitive effects of various regulatory proposals to restrict selective contracting. Two of these comments addressed 'any willing provider/freedom of choice' requirements for pharmacies.[44]
>
> Limitations on choice are unlikely to be so severe that consumers' access to pharmacy services is inadequate. Just as competitive forces encourage pharmacies to offer their best price and service combination to a payer to gain access to its subscribers, competition also encourages payers (and employers) to establish pharmacy service arrangements that offer the level of accessibility that subscribers prefer.[45]

In addition to antitrust enforcement by the federal antitrust agencies, the Courts have also addressed issues of market power for the different participants in the health care system. For example, in 1984, healthcare providers sued Blue Shield of Massachusetts (now Blue Cross Blue Shield ("BCBS-MA")), alleging that BCBS-MA exerted market power to secure noncompetitive prices from healthcare providers. The Court sided with BCBS-MA, as Judge

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44 *April 8, 2004 Letter to Rhode Island Attorney General Patrick C. Lynch and Deputy Majority Leader, Senator Juan M. Pichardo*, Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics ("FTC Letter to Rhode Island 2004"). In addition, the FTC noted: "An abundance of empirical evidence now exists demonstrating that, other things equal, selective contracting increases the intensity of competition among providers, which is manifested in lower prices paid by insurers to providers. The competition's intensity increases with the number of providers in the relevant market, and with the restrictiveness of the insurance contracts found in the market (i.e., HMOs, which have more limited panels than PPOs, induce more intense price competition among providers than would PPOs of equivalent size). These findings conform to economic theory. When insurers have a credible threat to exclude providers from their networks and channel patients elsewhere, providers have a powerful incentive to bid aggressively. Inclusion in a restricted panel offers the provider the prospect of substantially increased sales opportunities. Without such credible threats, however, providers have less incentive to bid aggressively, and even managed care organizations with large market shares may have less ability to obtain low prices." (FTC Letter to Rhode Island 2004).

45 FTC Letter to Rhode Island 2004.

Breyer (now a Supreme Court Justice) noted that antitrust laws were written to protect consumers from high prices, not necessarily from low prices:

> The Congress that enacted the Sherman Act saw it as a way of protecting consumers against prices that were too high, not too low. And, the relevant economic considerations may be very different when low prices, rather than high prices, are at issue. These facts suggest that courts should be cautious --reluctant to condemn too speedily – an arrangement that, on its face, appears to bring low price benefits to the consumer.[46]

While a few states (e.g., Washington, Texas, and Ohio) have passed antitrust exemptions for physicians, such legislation has wisely been rejected by several other states and at the federal level as expensive and unnecessary. The CBO estimated that proposed federal legislation to exempt physicians from antitrust scrutiny and allow collective bargaining would increase national expenditures on private health insurance by 2.6 percent when in full effect.[47] The CBO also predicted that such legislation would increase direct federal spending on healthcare programs such as Medicaid by $11.3 billion and decrease tax revenue by $10.9 billion over ten years.[48]

4. ANTITRUST EXEMPTIONS FOR INDEPENDENT PHARMACIES WILL INCREASE PHARMACEUTICAL COSTS

4.1. GEOGRAPHIC ACCESS REQUIREMENTS ALREADY LIMIT PBM NEGOTIATION EFFORTS

As motivation for their pursuit of antitrust exemptions, independent pharmacies claim that they are at a competitive disadvantage relative to chain pharmacies in negotiating with health insurers (or their PBMs). However, health insurers' geographic access requirements already provide rural pharmacies with a bargaining advantage over PBMs. Health plan sponsors, both public (e.g., Medicare) and private, require that beneficiaries have convenient access to covered health care services. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (known as the Medicare Modernization Act, or "MMA")

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46 Kartell v. Blue Shield, 749 F.2d 922, 930-31 (1st Cir. 1984), cert. denied, 471 U.S. 1029 (1985), as cited in: *Level Playing Fields in Health Care Markets*, speech delivered by FTC Chairman Robert Pitofsky to the National Health Lawyers Association, February 13, 1997.

47 Congressional Budget Office, "Cost Estimate: H.R. 1304, Quality Health Care Coalition Act of 1999, As Introduced on March 25, 1999," March 15, 2000 ("CBO Cost Study 2000"). Accessed at http://www.cbo.gov/showdoc.cfm?index=1885&sequence=0.

48 CBO Cost Study 2000. The CBO also noted that: "[a]t present, CBO cannot estimate the likely increase in the cost of health insurance for employees of state, local, and tribal governments."

established an outpatient prescription drug program known as Medicare Part D. Health care plans seeking to participate as carriers are required to create pharmaceutical networks that meet the following geographic access requirements:

- At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy;
- At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy; and
- At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy.[49]

Commercial health plans establish their own accessibility requirements for the members in their networks, typically including their desired or mandatory access requirements in their requests for proposals ("RFPs") to PBMs. This particular element of the contract is not usually negotiated, but established as a necessary condition to be considered for contracting negotiations.[50] As a result, a PBM's response to an RFP typically includes a report that estimates the distance between all of a plan sponsor's insureds and the prospective PBM's nearest pharmacy. Commercial geographic access requirements often follow the Medicare requirements, although a health care provider might occasionally offer lower rates to customers if they agree to slightly less restrictive accessibility requirements. While Medicaid programs generally do not specify precise access requirements, they typically offer broad networks.[51] To entice pharmacies to participate in the Medicaid program, state governments sometimes offer Medicaid reimbursement rates that are higher than those offered by commercial health insurers.[52] In fact, the National Community Pharmacists Association ("NCPA") found that the gross profit margin for Medicaid (20.8 percent) exceeded the commercial insurer gross margin (19.3 percent) by nearly 8 percent.[53]

As a result of the geographic distribution of retail pharmacy stores of all types, these geographic access requirements are typically most difficult for PBMs and health insurers to meet in rural locations,[54] where more than 50 percent of independent pharmacies are

49 This information is available through 42 CFR 423 Section 423.120; See also Appendix VII of the Medicare Prescription Drug Benefit Solicitation for Application from Prescription Drug Plans.

50 Based upon interviews with PBM industry personnel.

51 Medicaid reimbursements "must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." (42 CFR 447.204).

52 "To serve a diffuse population, states have generally set reimbursement rates high—at least compared with other third-party payers—to ensure that an ample number of pharmacies agree to serve Medicaid clients." Ronald A. Wirtz, "Cash, Check, or Third Party: Prescription Benefit Plans are Squeezing Retail Pharmacies," FedGazette, January 2006 ("Wirtz 2006b"), p. 4.

53 2006 NCPA Digest, p. 53.

54 For example, there are only about 230 retail pharmacies in Montana, where 10 counties have no retail pharmacies and 17 counties have a single retail pharmacy. Wirtz 2006a.

located.[55] It is not uncommon for commercial insurers to provide higher reimbursement levels (either by increasing the ingredient cost reimbursement or the dispensing fee, or both) to rural pharmacies, and some state Medicaid programs also explicitly employ differential reimbursement formulas that provide more generous reimbursements to rural pharmacies.[56] These increased reimbursement rates may be a result of their higher costs or may result from the local market power these isolated rural pharmacies possess. Which explanation dominates likely depends on the characteristics of the local market and pharmacy.[57]

4.2. The Structure to Facilitate Collective Negotiations by Independent Pharmacies Already Exists

Independent pharmacies employ Pharmacy Service Administrative Organizations, or "PSAOs,"[58] which represent a number of independent pharmacies, in order to reduce administrative costs of contracting and to gain advantages that accrue from a larger volume of activities (economies of scale). PSAOs sometimes represent independent pharmacies in contractual negotiations with entities such as PBMs or managed care organizations.[59]

Independent pharmacies often belong to more than one PSAO, although PBMs typically require that any given pharmacy interact with the PBM through a single PSAO.[60] In fact, rather than considering PSAOs a threat to reimbursement rates, PBMs typically prefer independent pharmacies to work through PSAOs, where feasible, because of the administrative efficiencies PSAOs provide to PBMs in building and maintaining pharmacy networks.

PBM support for PSAOs stems, in part, from the fact that, to date, PSAOs have not achieved significantly higher reimbursements for their independent and/or rural constituents because PBMs are not required to negotiate through them to build viable networks. While PSAO contracts occasionally achieve some small advantage in reimbursement relative to chain

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55 "Rural" is defined as an area with local population less than 20,000; see 2006 NCPA Digest, p. 61.

56 For example, as of December 2005 the Medicaid dispensing fee in Utah was higher for rural pharmacies ($4.40) than for urban pharmacies ($3.90). Similarly, Louisiana and Michigan had Medicaid reimbursement terms that differ for independent and chain pharmacies. See Centers for Medicare and Medicaid Services, "Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2005," accessed at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/08_MdPresReimInfo.asp.

57 While costs are often mentioned to be high for rural pharmacies, the 2006 NCPA Digest noted that rural pharmacies had the lowest average payroll expenses and the lowest operating expenses, and the highest profit of all independent pharmacies. See page 61.

58 PSAOs are sometimes known by other designations, such as "affiliations." Some PSAOs, such as IPC, are privately held, while others (e.g., United Drug) are owned by pharmaceutical wholesalers (e.g. McKesson).

59 *Medicare: Sponsors' Management of the Prescription Drug Discount Card and Transitional Assistance Benefit*, United States Government Accountability Office, January 13, 2006, fn. 24.

60 In such an arrangement, independent pharmacies might interact with different PBMs through different PSAOs.

pharmacies, these differentials have typically resulted from other considerations, including a sharing of administrative cost gains from collective representation of independent pharmacies. PBMs have not typically contracted with PSAOs that demand reimbursement terms for their member pharmacies that exceed competitive market levels. The historic willingness of individual pharmacies to defect from PSAOs or to join multiple PSAOs has limited any PSAO's efforts to achieve substantial reimbursement increases, as PBMs have maintained the ability to secure the participation of a sufficient number of pharmacies necessary to meet geographic access requirements.

4.3. Antitrust Exemptions to Independent Pharmacies will Increase Reimbursements to Independent Pharmacies and These Costs will be Passed on to Payers, Including Health Plans and Their Customers

The geographic access requirements and existence of PSAOs combine to create an environment in which antitrust exemptions would likely enable independent pharmacies to extract significantly higher reimbursements from PBMs and health insurers. With antitrust exemptions that enable independent pharmacies to use PSAOs or similar entities to bargain on their collective behalf, independent pharmacies are likely to be able to use and enhance their market power.[61]

As discussed above, regulatory agencies, primarily the FTC, have repeatedly noted that the PBM industry is highly competitive. The competitiveness of the PBMs has a critical economic consequence for who will bear the costs that would result from antitrust exemptions: any cost absorption by PBMs would be transitory. That is, competition among PBMs will result in increased costs being passed through to plan sponsors (health insurers and employers). As a result, health insurers, employers, and their insured members would see higher healthcare costs and/or a reduction in healthcare benefits. As noted by the FTC in consideration of Rhode Island bills that would eliminate selective contracting for pharmacy services:

> By eliminating an important form of competition in the market for pharmaceutical services, the Bills are likely to increase the cost of those services. These cost increases are likely to undermine the ability of some consumers to obtain the pharmaceutical services they need at a price they can afford. As a recent article in

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61 Rural pharmacies already possess substantial market power because they must often be included in networks in order for plans to meet geographic pharmacy access requirements for their enrollees. One might thus ask why an antitrust exemption confer additional benefits on rural pharmacies. There are a several responses: first, currently, even in rural areas, there is likely some competition with independent pharmacies in other areas. Second, the legislation would provide a unifying theme for PSAO negotiations, which currently reflect the fact that PBMs might resist negotiating with the pharmacies through the PSAOs if the terms are unfavorable. Similarly, in non-rural areas, where independent pharmacies face competition from chain stores, each individual pharmacy (independent or chain) exerts little market power. With an antitrust exemption, the independent pharmacies in urban areas could negotiate collectively, and given access requirements, it is unlikely that the PBMs could do without all independent pharmacies in these areas.

> Health Affairs noted, 'when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions.' Although the Bills appear intended to broaden access to pharmaceutical services, there is a significant probability they will have the opposite effect.[62]

As noted in the FTC's analysis, increasing the cost of PBM operations is expected to increase the costs to consumers and to lead potentially to decreased access to prescription services.

5. ANTITRUST EXEMPTIONS FOR INDEPENDENT PHARMACIES WILL INCREASE COSTS FOR PAYERS, INCLUDING HEALTH PLANS AS WELL AS PATIENTS BY UP TO $29.6 BILLION OVER FIVE YEARS

This study has estimated the likely cost increases that would likely result from provision of antitrust exemptions under two scenarios, namely allowing independent pharmacies to increase their commercial reimbursements to levels that:

- Result in gross margins on commercially insured prescriptions equaling the gross profit realized from Cash prescriptions, representing an 88 percent increase in the commercial gross profit rate (the "Potential cost increase" scenario);[63] or
- Equal the amount that North Dakota pharmacists demanded, through apparent collective efforts but in the absence of collective negotiation legislation, to participate in Medicare Part D pharmacy networks, representing a 32 percent increase in the commercial gross profit rate (the "Cost increase demanded in the absence of legislation" scenario).[64]

The impact that these scenarios have on total pharmacy costs to PBMs and their customers depends in part on how sensitive pharmacy customers are to price increases. The "price elasticity of demand" reflects how much patients reduce their consumption when the cost of prescription pharmaceuticals increases. If patients filled all their prescriptions regardless of cost, then there would be a direct, one-to-one relationship between the pharmacy's increase

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62 FTC Letter to Rhode Island 2004.

63 Based on median, rather than average, sales per pharmacy. See Section 7.

64 Pharmacies in North Dakota declined the reimbursement terms proposed by PBMs and noted instead that they might accept contracts with the following reimbursement terms: AWP – 10 percent plus $4.50 for branded drugs; Maximum Allowable Cost ("MAC") plus $3.00 for generic drugs; and AWP – 15 percent plus $3.00 for generic drugs that do not have MAC prices. According to *The Prescription Drug Benefit Cost and Plan Design Survey Report, 2005 Edition* (The Pharmacy Benefit Management Institute, Inc., sponsored by Takeda Pharmaceuticals North America, Inc., 2005), the average reimbursement terms for branded drugs in 2004 was AWP – 14.8 percent plus $1.95. (See page 4). This study uses the difference in the current and demanded reimbursement rate for branded drugs to characterize this scenario.

in prices and an increase in its net sales and profits.[65] However, as suggested by the FTC statements on proposed legislation related to the PBM business model, it is more reasonable to expect that patients will fill fewer prescriptions (i.e., spend less) as the costs of those prescriptions increase. As a result of the proposed legislation, if patients are sensitive to the price of their pharmaceuticals, they may forego beneficial pharmaceutical care, just as increases in the cost of health insurance increase the numbers of uninsured.

A summary of economic research published between 1973 and 1999 indicates that for a 10 percent increase in the cost of a prescription, the volume of prescriptions consumed falls by 2 to 3.5 percent.[66] For the purposes of our study, we assume that prescription consumption would fall by the midpoint of this range, or 2.7 percent (i.e., the price elasticity of demand for pharmaceutical prescriptions is -0.27).[67] Under this assumption, the cost increases of the antitrust exemptions are:[68]

Potential Impact of Independent Pharmacy Antitrust Exemption	**Total Cost Impact** ($ billions)	**Cost Impact on Commercial Sector** ($ billion)	**Cost Impact on Medicare Part D** ($ billions)	**Increase in Prescription Costs at Independent Pharmacies** (%)
Potential cost increases with proposed independent pharmacy antitrust exemptions	$29.6	$23.2	$6.4	11.8%
Cost increases demanded in absence of independent pharmacy antitrust exemptions	$9.2	$7.2	$2.0	3.6%

As a result, independent pharmacy antitrust exemptions are expected to increase costs to health plans and patients from $9.2 billion to $29.6 billion over five years (e.g., 2008-2012, if

65 For the purposes of this study, we do not consider the possibility of incremental effects to economies of scale or scope.

66 *The Cost of a Medicare Prescription Drug Benefit: A Comparison of Alternative*, Dana Goldman, Geoffrey Joyce, and Jesse Malkin, RAND, January 2002, pp. 7-8. In addition to assessing other literature, this article estimated a price elasticity of demand of -0.27 (that is, a 10 percent increase in price is expected to decrease the volume of prescriptions purchased by 2.7 percent).

67 This assumption means that patients would reduce spending on prescriptions by 2.7 percent if the cost of those prescriptions increased by 10 percent. The results based on alternative elasticity estimates are included below.

68 See the technical notes for an explanation of the five-year cost aggregation and assumptions of the cost model.

legislation passed in 2007).[69] The costs increases from independent pharmacy participation in Medicare Part D programs generate roughly 22 percent of these costs.

5.1. Cost Increases from Antitrust Exemptions Depend on Pharmacy Participation and the Requirements for Pharmacy Networks

In addition to the cost scenarios described above, the model of the costs of independent pharmacy antitrust exemptions also considers other factors that would affect the exemption costs. These factors derive from the particular form of the legislation or implementation of the antitrust exemption and the way in which pharmacies react to it, including:

- *The Effects of Medicare Part D on the payer mix of prescriptions filled at independent pharmacies*: The implementation of Medicare Part D increased the percentage of prescriptions reimbursed by third party payers by reducing the share of both Medicaid and Cash prescriptions.[70] Medicaid coverage of prescriptions fell as Part D shifted coverage for dual eligibles, or those beneficiaries who meet eligibility conditions for both Medicare and Medicaid, to Medicare. Before MMA, dual eligibles received out-patient prescription coverage from Medicaid, where they represented 14 percent of the Medicaid population and up to 40 percent of Medicaid spending.[71] According to researchers from the Centers for Medicare and Medicaid Services ("CMS"), Part D is largely responsible for a 36 percent reduction in Medicaid drug spending between 2005 and 2006.[72] Similarly, Medicare Part D also led to reductions in cash prescriptions. According to the Agency for Healthcare Research and Quality, Medicare beneficiaries accounted for slightly more than 50 percent of the out-of-pocket drug costs.[73] Based on recent CMS analysis, out-of-pocket prescription drug spending fell from 25 to 19 percent and private insurance prescription drug spending fell from 47 to 42 percent from 2005 to 2006.[74] Part D plans are administered by third party payers, either

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69 If patients were less sensitive to price increases, demonstrated by a price elasticity of demand of -0.20, the cost from full independent pharmacy participation would range from $10.0 billion to $32.4 billion over five years (increases of 4.0 to 12.9 percent of pharmaceutical spending at independent pharmacies). Alternatively, a larger price effect characterized by a price elasticity of demand of -0.35 would imply cost increases of $8.2 billion to $26.3 billion over five years (increases of 3.2 to 10.5 percent of pharmaceutical spending at independent pharmacies).

70 John A. Poisal, Christopher Truffer, Sheila Smith, Andrea Sisko, Cathy Cowan, Sean Keehan, Bridget Dickensheets, and the National Health Expenditure Accounts Projections Team, "Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact," Health Affairs Web-Exclusive Collection, February 21, 2007 ("National Health Expenditures 2007"), p. w250.

71 See, for example, Kaiser Commission on Medicaid Facts, "Dual Eligibles: Medicaid's Role for Low-Income Medicare Beneficiaries," The Henry J. Kaiser Family Foundation, February 2006.

72 National Health Expenditures 2007, p. w247. This study assumes that all changes in payer mix between 2005 and 2006 result from implementation of MMA.

73 *Chartbook #12: Outpatient Prescription Drug Expenses, 1999*. December 2003. Agency for Healthcare Research and Quality, Rockville, MD. http://www.meps.ahcpr.gov/mepsweb/data_files/publications/cb12/cb12.shtml. While out-of-pocket expenses include more than cash expenditures (e.g., prescription copayments), the lack of Medicare outpatient prescription drug coverage before MMA indicates that Medicare's share of cash payments would likely exceed 50 percent.

74 National Health Expenditures 2007, p. w250.

unilaterally or through contracts with PBMs. But for the proposed PBM collective bargaining legislation, it is assumed that the Medicare program would enjoy the negotiated discounts that third party payers currently obtain.

After the close of the of the May 15, 2006 enrollment period, 38.7 million Medicare beneficiaries had enrolled in Medicare Part D, leaving between 4 and 5 million without prescription drug coverage.[75] Earlier in the year, Secretary Mike Leavitt of the Health and Human Services Department stated that prescription drug coverage for Medicare beneficiaries might reach 90 percent in the program's first year.[76] To account for the effect of Medicare Part D on prescription drug payer mix, the cost model adjusts the pre-Medicare Part D payer mix provided by the 2006 NCPA-Pfizer Digest in two ways:[77]

1. Adjust the Medicaid and Cash prescription shares from the 2006 NCPA-Pfizer Digest to account for the 36 percent reduction in Medicaid drug spending and 24 percent reduction in out-of-pocket drug spending calculated by CMS personnel from 2005 to 2006;[78]

2. Assume that the reductions noted in Step 1 account for 90 percent of the total affect of Medicare Part D and adjust the cost model for Years 2 through 5 to account for 100 percent.

In order to remain conservative, this study does not estimate the effect of the increased prescription volume that is likely to coincide with the provision of pharmaceutical coverage under the MMA.

- *The extent of coordinated behavior among independent pharmacies*: The extent of participation of independent pharmacies in collective negotiation is uncertain. If rural pharmacies enjoy greater competitive advantage in negotiations with health insurers or PBMs due to the small number of pharmacies in rural areas and the presence of geographic access requirements, they may have different incentives than the independent pharmacies located in more competitive areas, where chain, supermarket, and mass merchandiser pharmacies are prevalent. As a result, not all independent pharmacies may negotiate collectively.

  For example, based on the scenario in which independent pharmacies increase prices on commercial prescriptions sufficiently to earn the same gross margin that they do on their cash-paying patients, the increased cost associated with full independent phar-

75 "Medicare Enrollment Figures Are Released by Government," Wall Street Journal, June 8, 2006.

76 "37 Million Medicare Beneficiaries Now Receiving Prescription Drug Coverage," News Release, United States Department of Health and Human Services, May 10, 2006.

77 According to the 2006 NCPA Digest, third-party payers accounted for 59 percent of prescriptions and Medicaid for 23 percent. See page 53.

78 National Health Expenditures 2007, p. w250. These reductions are applied to comparable payer categories from the 2006 NCPA Digest, which provides the "last glimpse of the independent community pharmacy marketplace before the implementation of Medicare Part D." (See page 3.)

macy participation would be $29.6 billion over five years.[79] If only rural independent pharmacies participate, costs would increase by $15.5 billion over five years.

- *The need for independent pharmacies in PBM networks*: As noted above, geographic access requirements force PBMs to include independent pharmacies in their provider networks. If costs of broad networks increase and PBMs negotiate new contracts with plan sponsors, a shrinking portion of the lives covered by PBMs may be subject to the access requirements, either because plan sponsors will relax the requirements in the face of increased costs or because PBMs will be less willing to actively manage lives covered by geographic requirements necessitating negotiations with independent pharmacies.[80]

  As a result, the cost model includes a parameter ("percent of covered lives with inflexible geographic access requirements") to account for the possibility that some commercial accounts could avoid the cost increases associated with antitrust exemptions. The model adjusts this value over time to account for both implementation and mitigation efforts. Actively managed lives are assumed to account for 100 percent of insured lives in the first year of implementation as health insurers or PBMs bear immediate responsibility for compliance with geographic access requirements, regardless of the level of management offered by the PBM to a particular plan sponsor. The cost model assumes that PBMs would reduce their exposure to independent pharmacies over time, reaching this minimum level of 60 percent after five years.[81]

6. CONCLUSION: ANTITRUST EXEMPTIONS WILL INCREASE COSTS OF AND REDUCE ACCESS TO HEALTH CARE

Calls for antitrust exemptions to allow independent pharmacies to negotiate collectively are unwarranted. Even if antitrust exemptions were an appropriate tool to address competitive imbalances between pharmacies and PBMs or health insurance plans, which they typically are not, no such competitive imbalance exists. In fact, regulatory authorities have explicitly noted the competitive nature of the PBM industry. To the extent that prices paid to pharmacies have been reduced, these price reductions have benefited consumers, who maintain adequate access to retail pharmacies. The antitrust laws are not designed to protect individual competitors that may be harmed by competition, but rather to insure that

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79 All estimates in this paragraph assume price elasticity of demand for prescriptions of -0.27.

80 Such behavior might change the geographic access requirement directly (e.g., by changing the percentage or patients that must live within a certain distance of a pharmacy) or by allowing alternative pharmacy options to service rural patients (e.g., mail order). Note, however, that while such behavior might avoid the cost increases associated with antitrust exemptions, the effect of the exemptions is still felt in resultant access reductions.

81 The model assumes that the percentage of covered lives with inflexible geographic access requirements decreases by the same amount (10 percent) in years 2, 3, and 4 to reach a level of 60 percent in year 5. In reality, another factor that might affect the speed of adjustment is the penalty or breach cost for noncompliance with geographic access requirements in the PBMs' contracts with plan sponsors.

consumer welfare is maintained through access to providers with reasonable prices and quality.

The financial health of independent pharmacies does not suggest that the segment is in danger of failing. While some individual stores may have closed, these closings appear more related to a shortage of qualified pharmacists than to the underlying financial condition of the stores. Independent pharmacies are profitable, and pharmaceutical sales to independent pharmacies have consistently increased.

The provision of antitrust exemptions, then, is effectively a wealth transfer program for independent pharmacies. The cost of such a transfer program to health payers and patients is expected to be up to $29.6 billion over five years, representing an increase of up to 11.8 percent. Costs for the Medicare Part D program alone will increase by up to $6.4 billion over five years. Including the reduction or elimination of access to health care for those affected by the cost increases would further increase the total cost of antitrust exemptions for independent pharmacies.

7. TECHNICAL NOTES

In general terms, this study relies on a model that estimates the costs of antitrust exemptions to independent pharmacies under several scenarios. In particular, the model is based on general financial information on independent pharmacies, including: median prescription sales per pharmacy,[82] gross profit margins for prescription sales, the total number of independent pharmacies,[83] the payer mix (i.e., the percentage of prescriptions paid by private insurers, Medicaid, and by patients (cash)), and the gross margin for each type of payer.[84]

7.1. NOTES ON FIVE YEAR ESTIMATES

This study calculates estimates the five-year costs of antitrust exemptions to independent pharmacies. The assumptions used to generate five year estimates:

- Changes in payer mix from implementation of Medicare Part D: As discussed above, this model assumes that changes to the payer mix observed by CMS (i.e., decreased

82 The 2006 NCPA Digest provides only median information for rural hospitals. This data limitation, combined with concerns that outliers may reflect data errors, motivated the use of medians in this analysis.

83 The 2006 NCPA Digest did not identify the number of independent pharmacies falling into the "rural" designation, instead stating that "More than 50 percent of community pharmacies are located in an area with a population of less than 20,000." (p. 61). According to the 2004 NCPA-Pfizer Digest, 32 percent of independent pharmacies contributing to the Digest were located in areas with a population exceeding 50,000. (*2004 NCPA-Pfizer Digest*, National Community Pharmacists Association, 2004, p. 61). When necessary, this study assumes that 60 percent of independent pharmacies are rural.

84 2006 NCPA Digest, pp. 6, 10-11, and 53.

Medicaid and out-of-pocket prescription drug spending) were captured between 2005 and 2006, but that the full affect of Medicare Part D will not be realized until the second year of the program. This study does not account for the expected increase in the number of prescriptions that will likely result from increased insurance coverage.

- Discounting future revenues and costs: The value of money changes over time – a $100 prescription is more valuable today than it will be a year from now. Economists use a discount rate to account for the reduced value of money in the future. This model assumes a discount rate of 10 percent.

7.2. Notes on Maintained Assumptions of the Independent Pharmacy Antitrust Exemption Cost Model

Finally, the cost model relies on several assumptions that describe the economic relationships underlying the cost estimates.

1. NCPA data are complete and accurate. The majority of data used for the cost model are provided by the 2006 NCPA Digest.[85]
2. The cost model assumes that legislation will limit collective bargaining activity to commercial accounts (as in H.R. 971), including Part D plans since they are administered by third party payers.
3. The effect on annual total costs declines year-by-year during the five year time period analyzed. This is because the increased costs resulting from pharmacy collective bargaining would be expected to alter the way in which PBMs respond to geographic access requirements during the RFP process. (Plan sponsors also likely to alter geographic access expectations if cost increases are significant).
4. Independent pharmacies are equally able to affect all reimbursement terms through collective negotiation. In particular, the model does not differentiate between ingredient cost, dispensing fee, or Maximum Allowable Cost ("MAC") reimbursement provisions.
5. The model offers no predictions on where cost increases will be absorbed. Rather, the analysis summarizes literature relevant to the competitiveness of PBMs, and uses economic theory to predict that the ultimate customers (employers and patients) will therefore bear the costs.
6. Independent pharmacies do not alter reimbursement demands due to loss of volume. As documented by NCPA, independent pharmacies enjoy a higher gross profit margin on non-pharmaceutical sales (34.2 percent) than on pharmaceuticals (22.7 percent).[86] This model assumes that independent pharmacies find it profit maximizing to maintain their reimbursement demands, despite any resulting loss in volume of pharmaceutical sales.

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85 Unlike most data used for consideration of healthcare cost or access issues, the 2006 NCPA Digest does not provide information necessary to assess the reliability of the reported data (e.g., survey response rate, treatment of outliers, quality assurance measures for financial estimates, etc.).

86 2006 NCPA Digest, p. 11.

7. The model considers only the costs that will result from collective negotiation by independent pharmacies on reimbursement terms. The model does not consider any restrictions on PBM business practices, nor does it consider any buy-side changes (e.g., from collective negotiation with wholesalers or manufacturers) resulting from collective negotiation by independent pharmacies. Such behavior would be additive to the costs estimated by this model.
8. Estimates of cost increases are less expensive than would be paying penalties. Depending on the contracts between PBMs and health plan sponsors, it might be the case that a PBM could operate, without breaching its contract with a plan sponsor, in violation of geographic access requirements. Such behavior would likely prompt a penalty payment to the plan sponsor. While it is unlikely that such behavior would persist for the five years of the study, the model assumes that the net cost of such behavior (including penalties, increased likelihood of breach, reduced probability of winning future accounts, etc.) exceeds the cost estimates generated by the model.
9. Per drug acquisition costs are constant for all payer types. In particular, the cost model assumes that independent pharmacies purchase drugs for the same price, regardless of the payer that will ultimately provide reimbursement for a prescription of that drug.

Individually, these assumptions have limited effect on the cost model, which is sufficiently flexible to provide sensitivity tests should the particular form of proposed legislation differ substantially from collective negotiation legislation like H.R. 971.

Appendix Table 1: Cost Projections for Antitrust Waivers to Independent Pharmacies
(Based on -0.27 Price Elasticity of Demand for Prescriptions)

	Year 1		Year 2[3]	
Cost Projections for Independent Pharmacies[1] (assuming no other changes to status quo)	**All independent pharmacies**	**Rural pharmacies[2]**	**All independent pharmacies**	**Rural pharmacies**
Total prescription sales per pharmacy (2005)	3,210,239	2,801,365	3,542,349	3,091,175
Total prescription gross margin per pharmacy (2005)	728,490	617,406	803,855	681,279
Gross margin percentage for prescriptions	22.7%	22.0%	22.7%	22.0%
Total number of independent pharmacies[4]	24,500		24,500	
Payer Mix for Independent Pharmacies, 2005[5]	**Percentage**	**Gross margin**	**Percentage**	**Gross margin**
Third-party payer[6]	71.6%	19.3%	73.0%	17.8%
Medicaid	14.7%	20.8%	13.8%	19.5%
Cash[7]	13.7%	36.2%	13.2%	37.4%
Percent of Lives Covered by Third-Party Payers (Excluding Federal Employees)[8]	62%		64%	
Percent of Covered Lives with Inflexible Geographic Access Requirements[9]	100%		90%	
Base Revenues for Cost Simulation	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Percent of all independent pharmacies included in simulation	100%	60%	100%	60%
Independent pharmacy TPP prescription sales ($ million)	49,029	25,670	55,316	28,962
Cost Simulation Scenarios	**Percent gross margin increase**	**Incremental percentage gross margin**	**Percent gross margin increase**	**Incremental percentage gross margin**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	88%	16.9%	110%	19.6%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	32%	6.3%	32%	6.3%
Effect of (-0.27) Price Elasticity of Demand for Prescriptions	**Elasticity effect**	**Incremental percentage gross margin**	**Elasticity effect**	**Incremental percentage gross margin**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	64%	12.4%	80%	15.5%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	24%	4.6%	24%	4.6%
Total Incremental Gross Margin Increases for TPP Prescriptions[11]	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	6,060	3,173	7,732	4,048
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	2,238	1,172	2,273	1,190
Resulting Total Prescription Sales	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	55,089	28,843	63,048	33,010
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	51,267	26,842	57,588	30,152
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	12.4%	12.4%	14.0%	14.0%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	4.6%	4.6%	4.1%	4.1%

Appendix Table 1: Cost Projections for Antitrust Waivers to Independent Pharmacies
(Based on -0.27 Price Elasticity of Demand for Prescriptions)

	Year 3[3]		Year 4[3]	
Cost Projections for Independent Pharmacies[1] (assuming no other changes to status quo)	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Total prescription sales per pharmacy (2005)	3,908,816	3,410,968	4,313,196	3,763,843
Total prescription gross margin per pharmacy (2005)	887,016	751,759	978,781	829,531
Gross margin percentage for prescriptions	22.7%	22.0%	22.7%	22.0%
Total number of independent pharmacies[4]	24,500		24,500	
Payer Mix for Independent Pharmacies, 2005[5]	**Percentage**	**Gross margin**	**Percentage**	**Gross margin**
Third-party payer[6]	73.0%	17.8%	73.0%	17.8%
Medicaid	13.8%	19.5%	13.8%	19.5%
Cash[7]	13.2%	37.4%	13.2%	37.4%
Percent of Lives Covered by Third-Party Payers (Excluding Federal Employees)[8]	64%		64%	
Percent of Covered Lives with Inflexible Geographic Access Requirements[9]	80%		70%	
Base Revenues for Cost Simulation	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Percent of all independent pharmacies included in simulation	100%	60%	100%	60%
Independent pharmacy TPP prescription sales ($ million)	61,038	31,959	67,353	35,265
Cost Simulation Scenarios	**Percent gross margin increase**	**Incremental percentage gross margin**	**Percent gross margin increase**	**Incremental percentage gross margin**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	110%	19.6%	110%	19.6%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	32%	6.3%	32%	6.3%
Effect of (-0.27) Price Elasticity of Demand for Prescriptions	**Elasticity effect**	**Incremental percentage gross margin**	**Elasticity effect**	**Incremental percentage gross margin**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	80%	15.5%	80%	15.5%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	24%	4.6%	24%	4.6%
Total Incremental Gross Margin Increases for TPP Prescriptions[11]	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	7,584	3,971	7,322	3,834
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	2,229	1,167	2,152	1,127
Resulting Total Prescription Sales	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	68,622	35,929	74,675	39,098
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	63,267	33,126	69,505	36,392
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	12.4%	12.4%	10.9%	10.9%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	3.7%	3.7%	3.2%	3.2%

Appendix Table 1: Cost Projections for Antitrust Waivers to Independent Pharmacies
(Based on -0.27 Price Elasticity of Demand for Prescriptions)

	Year 5[3]	
Cost Projections for Independent Pharmacies[1] (assuming no other changes to status quo)	**All independent pharmacies**	**Rural pharmacies**
Total prescription sales per pharmacy (2005)	4,759,411	4,153,225
Total prescription gross margin per pharmacy (2005)	1,080,039	915,349
Gross margin percentage for prescriptions	22.7%	22.0%
Total number of independent pharmacies[4]	24,500	
Payer Mix for Independent Pharmacies, 2005[5]	**Percentage**	**Gross margin**
Third-party payer[6]	73.0%	17.8%
Medicaid	13.8%	19.5%
Cash[7]	13.2%	37.4%
Percent of Lives Covered by Third-Party Payers (Excluding Federal Employees)[8]	64%	
Percent of Covered Lives with Inflexible Geographic Access Requirements[9]	60%	
Base Revenues for Cost Simulation	**All independent pharmacies**	**Rural pharmacies**
Percent of all independent pharmacies included in simulation	100%	60%
Independent pharmacy TPP prescription sales ($ million)	74,321	38,913
Cost Simulation Scenarios	**Percent gross margin increase**	**Incremental percentage gross margin**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	110%	19.6%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	32%	6.3%
Effect of (-0.27) Price Elasticity of Demand for Prescriptions	**Elasticity effect**	**Incremental percentage gross margin**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	80%	15.5%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	24%	4.6%
Total Incremental Gross Margin Increases for TPP Prescriptions[11]	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	6,925	3,626
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	2,036	1,066
Resulting Total Prescription Sales	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	81,246	42,539
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	76,356	39,979
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	9.3%	9.3%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	2.7%	2.7%

Appendix Table 1: Cost Projections for Antitrust Waivers to Independent Pharmacies
(Based on -0.27 Price Elasticity of Demand for Prescriptions)

Cost Projections for Independent Pharmacies[1] (assuming no other changes to status quo)				
Total prescription sales per pharmacy (2005)				
Total prescription gross margin per pharmacy (2005)				
Gross margin percentage for prescriptions				
Total number of independent pharmacies[4]				
Payer Mix for Independent Pharmacies, 2005[5]				
Third-party payer[6]				
Medicaid				
Cash[7]				
Percent of Lives Covered by Third-Party Payers (Excluding Federal Employees)[8]				
Percent of Covered Lives with Inflexible Geographic Access Requirements[9]				
			Net Present Value With discount rate of 10 percent	
Base Revenues for Cost Simulation				
Percent of all independent pharmacies included in simulation				
Independent pharmacy TPP prescription sales ($ million)			251,126	131,485
Cost Simulation Scenarios				
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)				
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])				
Effect of (-0.27) Price Elasticity of Demand for Prescriptions				
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)				
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	**Nominal**		**Net Present Value With discount rate of 10 percent**	
Total Incremental Gross Margin Increases for TPP Prescriptions[11]	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	35,623	18,652	29,588	15,492
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	10,927	5,721	9,154	4,793
Resulting Total Prescription Sales	**All independent pharmacies**	**Rural pharmacies**	**All independent pharmacies**	**Rural pharmacies**
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)	342,680	179,420	280,714	146,976
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])	317,984	166,490	260,280	136,277
Potential cost increases (independent pharmacy gross margin for TPP scripts increase to cash levels)			11.8%	11.8%
Cost increases attempted without legislation (gross margin for TPP scripts increase to ND requested rate[10])			3.6%	3.6%

Notes

[1] Independent pharmacies are defined as those pharmacies that are not publicly owned or traded. Based on median sales, per 2006 NCPA-Pfizer Digest, pp. 10, 61.

[2] "Rural" pharmacies use the National Community Pharmacy Association ("NCPA") measurement of pharmacies located in areas with population less than 20,000. According to the 2006 NCPA-Pfizer Digest, more than 50 percent of community pharmacies fall into this category (see p. 61). According to the 2004 NCPA-Pfizer Digest, 32 percent of independent pharmacies contributing to the Digest were with a population exceeding 50,000. This estimate assumes that 60 percent of independent pharmacies are rural.

[3] Total prescription sales per pharmacy and total prescription gross margin per pharmacy for all independent pharmacies and rural pharmacies for years 2 through 5 were calculated by projecting the simple average annual rate of prescription drug sales growth per pharmacy (10.3 percent) from the 2006 NCPA-Pfizer Digest over the last five years. (2006 NCPA-Pfizer Digest, p. 7.) In comparison, the government increased prescription drug spending a similar period by 12.5 percent. See *Trends and Indicators in the Changing Health Care Marketplace - National Health Expenditures and their share of Gross Domestic Product, 1960-2004*, Kaiser Family Foundation, accessed at www.kff.org. However, the results of this study are nearly insensitive to use of the Kaiser growth rate.

[4] 2006 NCPA-Pfizer Digest, p. 6.

[5] 2006 NCPA-Pfizer Digest, Table 14, p. 53. The cost model also assumes that 10 percent of third-party payer expenditures are for government employees and are thus excluded from cost estimates, as this was the case for H.R. 1671 and is expected to be a common feature of such legislation.

[6] The implementation of Medicare Part D increased the percentage of prescriptions reimbursed by third party payers and reduced the share of both Medicaid and Cash prescriptions. As discussed in Section 5.1, the cost model uses prescription shares (for third-party payers, Medicaid, and Cash) provided by the 2006 NCPA-Pfizer digest (p. 52, see footnote 5 above). Year 1 of the cost model applies a 36 percent reduction to the Medicaid share of prescriptions and a 24 percent reduction to the Cash share of prescriptions, based on the Medicaid and Out-of-pocket reductions associated with the Medicare Part D program, as documented by John A. Poisal, Christopher Truffer, Sheila Smith, Andrea Sisko, Cathy Cowan, Sean Keehan, Bridget Dickensheets, and the National Health Expenditure Accounts Projections Team, "Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact," Health Affairs Web-Exclusive Collection, February 21, 2007 ("National Health Expenditures 2007"), p. w250. The cost model assumes that the National Health Expenditures information captured 90 percent of the effect of Medicare Part D in Year 1; Years 2 through 5 assume 100 percent of the full effect of Medicare Part D.

[7] Gross profit for Cash payers calculated based on the the profit necessary to generate the total reported prescription gross profit rate (2006 NCPA-Pfizer Digest, p. 11) based on the established mix of payers and gross margins for third-party and Medicaid prescriptions (2006 NCPA-Pfizer Digest, p. 53).

[8] In 1999, Federal employees accounted for 8.8 percent of national health expenditures, while private spending accounted for 55.9 percent of national health expenditures. As a result, this model assumes that the 15.7 percent of commercial insurance expenditures for Federal employees based on pre-MMA payer mix would be exempt from collective negotiations by independent pharmacies (as Federal programs were exempted from H.R. 1761). Applied to the 59 percent of prescriptions reimbursed by third party payers (NCPA-Pfizer Digest 2005, p. 6) before implementation of Medicare Part D, the cost model assumes that 9.26 percent of commercial prescriptions represent Federal employees and are thus exempted from collective bargaining by independent pharmacies under the proposed waivers. For details, see: Steffie Woolhandler and David U. Himmelstein, "Paying for National Health Insurance – And Not Getting It," *Health Affairs*, July/August 2002, pp. 88-98; and Centers for Medicare and Medicaid Services, Office of the Actuary, "National Health Expenditure Data," available at: http://www.cms.hhs.gov/NationalHealthExpendData/02 NationalHealthAccountsHistorical.asp#TopOfPage

[9] Assumed to decrease to 60 percent over five years as PBMs reduce their exposure to independent pharmacies over time, using new contract cycles to address cost concerns with plan sponsors. See Section 5.1.

[10] In early 2005 North Dakota pharmacies returned the same form letter to PBMs attempting to create networks for Medicare Part D. These form letters rejected the reimbursement terms proposed by PBMs and noted instead that pharmacies might accept contracts with the following reimbursement terms: AWP – 10 percent plus $4.50 for branded drugs; Maximum Allowable Cost ("MAC") plus $3.00 for generic drugs; and AWP – 15 percent plus $3.00 for generic drugs that do not have MAC prices. (See Inside Washington Publishers *Inside CMS*, Vol. 8, No. 11, June 2, 2005). According to *The Prescription Drug Benefit Cost and Plan Design Survey Report, 2005 Edition* (The Pharmacy Benefit Management Institute, Inc., sponsored by Takeda Pharmaceuticals North America, Inc., 2005), the average reimbursement terms for branded drugs in 2004 was AWP – 14.8 percent plus $1.95. (See page 4). This study uses the difference in the current and demanded reimbursement rate for branded drugs to characterize this scenario

[11] Calculated as total prescription revenue for non-government third party payer prescriptions for percentage of lives with inflexible geographic access requirements, multiplied by the increase in the third-party payer gross margin.

Mr. CONYERS. Thank you very much, Dr. Rankin.

We really have some wide-ranging testimony here this morning.

We have a third witness who has a great deal of background. Attorney David Wales is the Deputy Director of the Bureau of Competition at the Federal Trade Commission. He has also served as Counsel to the Assistant Attorney General in the Antitrust Division of the Department of Justice. And he has also privately practiced as an antitrust lawyer at Cadwalader, Wickersham & Taft and Shearman & Sterling. In other words, he has a long career in this area of antitrust.

And we're very pleased that you could join us this morning. Welcome to the Committee.

TESTIMONY OF DAVID WALES, DEPUTY DIRECTOR, BUREAU OF COMPETITION, FEDERAL TRADE COMMISSION

Mr. WALES. Thank you very much, Chairman. It's a pleasure to be here today.

Chairman Conyers, Ranking Member Keller and Members of the Task Force, I am David Wales, deputy director of the Federal Trade Commission's Bureau of Competition. I appreciate the opportunity to appear today to present the Commission's views on H.R. 971, the Community Pharmacy Fairness Act of 2007.

Let me first start by saying that my oral presentation and responses today are my own and do not necessarily reflect the views of the Commission or any commissioner.

Health-care markets are complex and dynamic, and the market for pharmacy services is no exception. The Commission is mindful of the challenges and economic pressures faced by small drug stores brought on by changes in the health care sector. Caring pharmacists across the Nation work with dedication to serve the needs of patients, and we do not question the sincerity of those raising concerns about the quality of patient care. But the solution to the concerns raised by pharmacies is not to give them immunity from the antitrust rules that guide our economy.

The Commission is charged with and takes very seriously its obligation to enforce the antitrust laws. And it acts to protect consumers by addressing anticompetitive action in each of the markets it reviews, including the markets for pharmacy and pharmacy benefit management services and other vital products and services in the health care industry.

H.R. 971 would create an exemption from the antitrust laws to allow to allow pharmacies to engage in collective bargaining to secure higher fees and more favorable contract terms from health plans.

Simply put, the Commission opposes legislation, because the exemption threatens to raise prices to consumers, including for seniors, for much-needed medicine. It also threatens to increase costs to both private and employers who provide health care insurance to employees, potentially reducing those benefits, and also to the Federal Government, which is projected to have paid over 30 percent of the cost of prescription drugs in 2006 alone. Importantly, the proposed bill threatens these harms without any assurance of higher-quality care for consumers.

At various times since the advent of active antitrust enforcement in health care in the 1970's, health care providers have sought an antitrust exemption. In 1998 and 1999, then-Chairman Robert Pitofsky testified on behalf of the FTC, opposing similar bills that would have applied to all health care professionals. Although those bills and others seeking antitrust exemptions have differed in their scope or details, they all have sought some form of antitrust immunity for anticompetitive conduct that would tend to raise the prices of health care services.

The Congressional Budget Office concluded, for example, that, if enacted, the 1999 exemption bill would significantly increase direct spending on pharmaceuticals both by private payers and under various Government programs.

Just this year, the Antitrust Modernization Commission, the body enacted by Congress to evaluate the application of our antitrust laws, addressed the subject of antitrust exemptions. The AMC urged that Congress exercise caution, pointing out that antitrust exemptions typically create economic benefits that flow to a small, concentrated group of interested groups, while the costs of these exemptions are widely disbursed, usually passed on to a large population of consumers through higher prices, reduced output, lower quality and reduced innovation.

Accordingly, the AMC recommended such statutory immunities be granted rarely and only where proponents have made a clear case that exempting otherwise unlawful conduct is necessary to satisfy a specific societal goal that trumps the benefit of free-market competition to consumers and the U.S. Economy in general.

Is the proposed exemption for pharmacies in H.R. 971 one of those rare instances in which the societal benefits from dispensing with antitrust rules in the normal competitive process exceed the costs? In Federal Trade Commission's view, it is not. The bill would immunize price-fixing and boycotts to enforce fee and other contract demands, conduct that would otherwise amount to clear antitrust violations.

Experience teaches that such conduct can be expected to increase health care costs both directly through higher fees paid to pharmacies and less directly by collective obstruction of cost-containment strategies of purchasers. These higher costs would fall on consumers, those employers who purchase pharmaceuticals and other products on behalf of their employees, and Government assistance programs. Importantly, making prescription drug coverage more costly means some Americans will actually have to do without important needed drugs.

In addition, although H.R. 971 aims to ensure and foster continued patient safety and quality of care, there is no guarantee that the proposed exemption would further these goals. Antitrust immunity not only would grant competing stores a powerful weapon to obstruct innovative arrangements for the delivery and financing of pharmaceuticals, but it also dull competitive pressures that drive pharmacies to improve quality and efficiency in order to compete more effectively.

Moreover, nothing in the bill requires that the collective bargaining it authorizes be directed to improving patient safety or

quality, rather that merely increasing pharmacies' revenues from payers.

If Congress concludes the difficulties facing small pharmacies require legislative solution, then one tailored to the specific problem is called for, not a sweeping antitrust exemption that may bring with it greater harm.

Again, I appreciate the opportunity to testify before you today. And I'd be happy to answer questions. Thank you.

[The prepared statement of Mr. Wales follows:]

PREPARED STATEMENT OF DAVID WALES

Prepared Statement of
the Federal Trade Commission

Before the
Antitrust Task Force
of the Committee on the Judiciary
United States House of Representatives

Concerning
H.R. 971
"The Community Pharmacy Fairness Act of 2007"

October 18, 2007

Chairman Conyers, Ranking Member Keller, and Members of the Task Force, I am David Wales, Deputy Director of the Federal Trade Commission's Bureau of Competition. I appreciate the opportunity to present the Commission's views on H.R. 971, "The Community Pharmacy Fairness Act of 2007."[1] This bill would create an exemption from the antitrust laws to allow pharmacies to engage in collective bargaining to secure higher fees and more favorable contract terms from health plans. Simply put, although the Commission is sympathetic to the difficulties independent and family pharmacies face, the exemption threatens to raise prices to consumers, especially seniors, for much-needed medicine. It also threatens to increase costs to private employers who provide health care insurance to employees, potentially reducing those benefits, and to the federal government, which was projected to have paid over 30 percent of the costs of prescription drugs in 2006,[2] all without any assurance of higher quality care. For these reasons, the Commission opposes the legislation.

At various times since the advent of active antitrust enforcement in health care in the 1970s, health care providers have sought an antitrust exemption. In 1998 and 1999, then Chairman Robert Pitofsky testified on behalf of the Commission opposing similar bills that would have applied to all health care professionals.[3] Although those bills and others seeking

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[1] This written statement represents the views of the Federal Trade Commission. My oral presentation and responses to questions are my own and do not necessarily reflect the views of the Commission.

[2] Centers for Medicare and Medicaid Services, Office of the Actuary, Table 11, National Health Expenditures Projections 2006-2016 (2007), *available at* http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf.

[3] *See* Testimony of Robert Pitofsky, Chairman, Federal Trade Commission on H.R. 1304, the "Quality Health-Care Coalition Act of 1999" (June 22, 1999); Testimony of Robert Pitofsky, Chairman, Federal Trade Commission on H.R. 4277, the "Quality Health-Care Coalition Act of 1998" (July 29, 1998).

antitrust exemptions have differed in their scope or details, they all have sought some form of antitrust immunity for anti-competitive conduct that would tend to raise the prices of health care services. The Congressional Budget Office concluded, for example, that, if enacted, the 1999 exemption bill would significantly increase direct spending on pharmaceuticals both by private payers and under various government programs.[4] Recognizing that many American consumers already face difficult health care choices in the market, Congress wisely has declined to adopt such exemption proposals, which only would add to consumers' difficulties.

Just this year the Antitrust Modernization Commission ("AMC") – the body created by Congress to evaluate the application of our nation's antitrust laws – addressed the subject of antitrust exemptions. The AMC urged that Congress exercise caution, pointing out that antitrust exemptions typically "create economic benefits that flow to small, concentrated interest groups, while the costs of the exemption are widely dispersed, usually passed on to a large population of consumers through higher prices, reduced output, lower quality, and reduced innovation."[5] Accordingly, the AMC recommended that such statutory immunities be granted "rarely" and only where proponents have made a "clear case" that exempting otherwise unlawful conduct is "necessary to satisfy a specific societal goal that trumps the benefit of a free market to consumers and the U.S. economy in general."[6]

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4 *See* notes 32 and 33, *infra*, and accompanying text.

5 Antitrust Modernization Commission, Report and Recommendations (April 2007) at 335, *available at* http://www.amc.gov/report_recommendation/toc.htm.

6 *Id.*

Is the proposed exemption for pharmacies in H.R. 971 one of those rare instances in which the societal benefits from dispensing with antitrust rules and the normal competitive process exceed the costs? In the Federal Trade Commission's view, it is not. The bill would immunize price-fixing and boycotts to enforce fee and other contract demands, conduct that would otherwise amount to blatant antitrust violations. Experience teaches that such conduct can be expected to increase health care costs, both directly through higher fees paid to pharmacies, and less directly by collective obstruction of cost containment strategies of purchasers. These higher costs would fall on consumers, employers – both public and private – who purchase pharmaceuticals and other products on behalf of their employees, and government assistance programs.

In addition, although the stated purpose of H.R. 971 is "[to] ensure and foster continued patient safety and quality of care," the Commission believes that the proposed exemption would not further these goals. Indeed, antitrust immunity not only would grant competing sellers a powerful weapon to obstruct innovative arrangements for the delivery and financing of pharmaceuticals, but also would dull competitive pressures that drive pharmacies to improve quality and efficiency in order to compete more effectively. Moreover, nothing in the bill requires that the collective bargaining it authorizes be directed at improving patient safety or quality, rather than merely increasing pharmacies' revenues from payers.

Health care markets are complex and dynamic, and pharmacy is no exception. The Commission is mindful of the challenges aud economic pressures faced by small pharmacies, brought on by changes in the health care sector. Caring pharmacists across the nation work with dedicatiou to serve the needs of patients, and we do not question the sincerity of those raising

concerns about the quality of patient care. But the solution to the concerns raised by pharmacies is not to give them immunity from the antitrust rules that guide our economy. If Congress concludes that the difficulties facing small pharmacies require a legislative solution, then one tailored to the specific problem is called for, not a sweeping antitrust exemption that may bring with it greater harm.

I. FTC Experience with Prescription Drug Competition

Competition in prescription drug markets occurs in the context of a complex web of relationships among physicians, patients, drug manufacturers, wholesalers, retail pharmacies, and various entities involved in pharmaceutical benefit programs, such as health insurers and health plans sponsored by employers, unions, and others. In addition, health plans often rely on pharmacy benefit managers (known in the industry as "PBMs"), which developed in response to the desire of purchasers to manage the cost and quality of the drug benefits provided to plan members.

The Commission's analysis of H.R. 971 is informed by a broad range of law enforcement activity, research, and regulatory analysis that it has undertaken as it seeks to protect competition and consumers in the pharmaceutical sector. The FTC has conducted numerous law enforcement

investigations, some resulting in challenges, involving drug manufacturers,[7] wholesalers,[8] and retailers.[9] In addition, Commission staff have done empirical studies and economic analyses of the pharmaceutical industry[10] and have analyzed competitive issues raised by proposed state and federal regulations affecting the industry.[11] Competition in the pharmaceutical sector was one of the subjects addressed in a series of joint FTC/Department of Justice hearings in 2003, and in an

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[7] *See, e.g.*, *Actavis Group/Abrika Pharmaceuticals, Inc.*, C-4190 (consent order issued May 18, 2007) (http://www.ftc.gov/os/caselist/0710063/index.shtm); *Watson Pharmaceuticals Inc./Andrx Corp.*, C-4172 (consent order issued December 6, 2006) (http://www.ftc.gov/os/caselist/0610139/index.htm); *Schering-Plough Corp.*, 2003 FTC LEXIS 187 (FTC Dec. 8, 2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006); *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004) (stipulated judgment); *FTC v. Mylan Labs., Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999).

[8] *See, e.g.*, *Federal Trade Commission v. Cardinal Health, Inc. and Bergen Brunswig Corp./ Federal Trade Commission v. McKesson Corp. and Amerisource Health Corp*, 12 F. Supp. 2d 34 (D.D.C. 1998) (http://www.ftc.gov/os/caselist/ca98595ddc.htm).

[9] *See, e.g.*, *Rite Aid Corp./The Jean Coutu Group, Inc.*, C-4191 (consent order issued June 1, 2007) (http://www.ftc.gov/os/caselist/0610257/0610257.shtm); *CVS Corporation/Revco*, 124 F.T.C. 161 (1997) (consent order).

[10] *See, e.g.*, Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002), *available at* http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf; Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (March 1999), *available at* http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

[11] *See, e.g.*, FTC Staff Comment to the Hon. Nelie Pou Concerning New Jersey A.B. A-310 to Regulate Contractual Relationships Between Pharmacy Benefit Managers and Health Benefit Plans (April 2007), *available at* http://www.ftc.gov/opp/advocacy_date.shtm; Letter from FTC staff to Virginia Delegate Terry G. Kilgore (Oct. 2, 2006), *available at* http://www.ftc.gov/be/V060018.pdf; Comments of the FTC Staff Before the FDA In the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion (May 10, 2004), *available at* http://www.ftc.gov/os/2004/05/040512dtcdrugscomment.pdf.

ensuing report on health care competition law and policy issued by the agencies in 2004.[12] In 2005, the Commission reported the findings of an in-depth empirical study of PBM ownership of mail order pharmacies,[13] and the staff is currently conducting a study regarding the competitive effects of branded drug firms' use of "authorized generics."[14]

II. The Proposed Exemption

H.R. 971 would grant "independent pharmacies" broad antitrust immunity to band together and negotiate collectively with health plans.[15] Under the proposed law, groups of independent pharmacies would be treated like a bargaining unit of a labor union operating pursuant to federal labor laws. As we discuss below, this proposed exemption from the antitrust laws, like previous proposed antitrust exemptions, would permit price fixing, coercive boycotts, and other anti-competitive conduct likely to result in significant harm to consumers. Otherwise competing pharmacies could agree on the prices and other terms they would accept from health plans, and collectively refuse to deal with plans that did not accede to their contract demands.[16]

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[12] *See* Federal Trade Commission and Department of Justice, *Improving Health Care: a Dose of Competition*, Chapter 7 (July 2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[13] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005), *available at* http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[14] *See* 71 Fed. Reg. 16,779 (April 4, 2006); 72 Fed. Reg. 25,304 (May 4, 2007).

[15] An independent pharmacy covered by the bill is any pharmacy not owned or operated by a "publicly-traded company."

[16] Section 2 (e), entitled "Limitation on Exemption," states that the bill would not immunize any "agreement or otherwise unlawful conspiracy that excludes, limits the participation or reimbursement of, or otherwise limits the scope of services to be provided by any independent pharmacy . . . with respect to the performance of services that are within their scope

Antitrust law condemns such conduct because it harms competition and consumers – raising prices for health care services and health care insurance coverage, and reducing consumers' choices. Public and private programs that purchase or pay for pharmaceuticals for consumers are likely to have to pay more as a result of the anti-competitive conduct the bill would authorize, and those higher costs, in turn, could increase the costs or lessen the scope or availability of such programs for consumers.

H.R. 971 is modeled on a previous antitrust exemption bill that passed the House in 2000 and covered all health care professionals, including pharmacists. The Commission opposed that bill, as did the Department of Justice, the Antitrust Section of the American Bar Association, health care economists, employers, health plans, consumer groups, and even some health care providers. They did so on the grounds that the exemption would cause substantial harm to consumers, raising prices without any certainty of improved quality, and was not necessary to protect legitimate, pro-competitive cooperative arrangements. While H.R. 971 is limited to a single class of health care providers, it raises the same fundamental issues as the previous exemption bill. Moreover, if enacted, it would invite other health care providers to seek similar antitrust immunity.

Although styled as a labor exemption, the antitrust immunity that H.R. 971 would confer bears no relation to federal labor policy. The labor exemption is limited to the

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of practice as defined or permitted by relevant law or regulation." While it is unclear exactly what this provision is intended to carve out, it does not appear to limit pharmacies' immunity for boycotts of purchasers or payers in order to force price concessions.

employer-employee context; it does not protect combinations of independent business people.[17] H.R. 971, however, would override the distinction Congress drew in the labor laws between employees and independent contractors. Unlike the labor law system, H.R. 971 also lacks the exclusions from protected negotiations for subjects unrelated to the intended purpose of those laws, as well as the oversight of the process by the National Labor Relations Board.

Moreover, the creation of a labor exemption for pharmacies is offered as a way to remedy matters that collective bargaining was never intended to address. The stated goal of H.R. 971 is to promote the safety and quality of patient care. The labor exemption, however, was not created to solve issues regarding the ultimate safety or quality of products or services that consumers receive. Collective bargaining rights are designed to raise the incomes and improve the working conditions of union members. The law protects, for example, the United Auto Workers' right to bargain for higher wages and better working conditions, but we do not rely on the UAW to bargain for safer, more reliable, or more fuel-efficient cars. Congress has addressed those types of concerns in other ways, as well as relying on competition in the market among automobile manufacturers to encourage product improvements. Patient care issues in the delivery of pharmacy services deserve serious consideration, but a labor exemption is ill-suited to the task.

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[17] *See, e.g., Columbia River Packers Ass'n v. Hinton*, 315 U.S. 143 (1942); *United States v. Women's Sportswear Mfg. Ass'n*, 336 U.S. 460 (1949); *American Medical Ass'n v. United States*, 317 U.S. 519, 533-36 (1943) (rejecting assertions that the labor exemption to the antitrust laws applied to joint efforts by independent physicians and their professional associations to boycott an HMO in order to force it to cease operating). NLRA Section 2 (3) gives the right to bargain collectively only to "employees." The 1947 Taft-Hartley amendments to the NLRA included a provision expressly stating that the term "employee" does not include "any individual having the status of an independent contractor." 29 U.S.C. § 152 (3).

In sum, H.R. 971 is designed to confer the labor exemption on parties whose situations are vastly different from those eligible for the exemption under long-standing and well-established principles of labor law. Instead, it would merely grant private businesses a broad immunity to present a "united front" when negotiating price and other terms of dealing with health plans, without any efficiency benefits for consumers or any regulatory oversight to safeguard the public interest.

III. The Exemption's Likely Effects

The proposed exemption can be expected to increase health care costs. There should be little dispute that the collective negotiations authorized by H.R. 971 likely would result in health plans' paying more to pharmacies – indeed that has been the intended and actual effect of such conduct in the cases involving collective negotiation by competing pharmacies that the Commission previously has brought.

The Commission's experience indicates that the conduct that the proposed exemption would allow could impose significant costs on consumers, private and governmental purchasers, and taxpayers, who ultimately foot the bill for government-sponsored health care programs. Past antitrust challenges to collective negotiations by health care professionals show that groups have often sought fee increases of 20 percent or more.[18] For example, in 1998, an association of approximately 125 pharmacies in northern Puerto Rico settled FTC charges that the association

[18] *See, e.g., Asociacion de Farmacias Region de Arecibo*, 127 F.T.C. 266 (1999) (consent order) (22 percent higher); *Advocate Health Partners, et al.*, C-4184 (consent order issued Feb. 7, 2007) (20-30 percent higher); *Health Care Alliance of Laredo*, C-4158 (consent order issued March 23, 2006) (30 percent higher regarding one payer; 20-90 percent higher for another payer, depending on the particular procedure); *San Juan IPA, Inc.*, 139 F.T.C. 513 (2005) (consent order) (up to 60 percent higher), all available at http://www.ftc.gov/bc/healthcare/antitrust/commissionactions.htm.

fixed prices and other terms of dealing with third-party payers, and threatened to withhold services from Puerto Rico's program to provide health care services for indigent patients.[19] According to the complaint, the association demanded a 22 percent increase in fees, threatened that its members would collectively refuse to participate in the indigent care program unless its demands were met, and thereby succeeded in securing the higher prices it sought. In another action in which the target of pharmacy collective price negotiations was a state program to assist the poor, the Commission charged that institutional pharmacies serving Medicaid patients in Oregon long-term care facilities agreed on the prices they would accept from the Oregon State Health Plan and negotiated collectively to raise reimbursement rates.[20]

Government-sponsored employee health benefit plans also have been victims of pharmacy boycotts. For example, in 1989 the Commission sued pharmacies in New York for conspiring to boycott the New York State Employees Prescription Plan to force an increase in reimbursement rates.[21] An administrative law judge found that the collective fee demands of the pharmacists cost the State of New York an estimated $7 million.[22] Other FTC actions challenged similar boycotts by pharmacies to obtain higher fees from government employee health plans,

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19 *Asociacion de Farmacias Region de Arecibo*, *supra* note 18.

20 *See Institutional Pharmacy Network*, 126 F.T.C. 138 (1998) (consent order).

21 *Peterson Drug Company of North Chili, New York, Inc.*, 115 F.T.C. 492 (1992) (opinion and order); *Chain Pharmacy Assn of NY State, Inc.*, 114 F.T.C. 327 (1991) (consent order); *Empire State Pharmaceutical Society, Inc.*, 114 F.T.C. 152 (1991) (consent order); *Pharmaceutical Society of the State of New York, Inc.*, 113 F.T.C. 661 (1990) (consent order).

22 *Peterson Drug*, 115 F.T.C. at 540.

including the Baltimore City employees' prescription-drug plan,[23] and a prescription drug program offered through a Colorado state health plan covering both union and salaried employees and retirees.[24] H.R. 971 would permit privately-held pharmacies to pursue this type of conduct without fear of antitrust challenge, and therefore likely would encourage pharmacies to engage in such actions.

Absent a sufficient number of alternative providers acceptable to the health plan and its consumer members, a health plan will have no choice but to accede to such fee demands, or it will not have a marketable pharmacy network to offer. Most PBMs, for example, contract with 90 percent of the retail pharmacies in the region they serve.[25] At the same time, the ability to exclude certain pharmacies from a network can foster both more competitive bargaining and certain economies of scale for businesses that are included in a network.[26] Moreover, payers may seek to limit the number of pharmacies with which they contract not only to induce more aggressive price competition among pharmacies, but also because their administrative costs might be lower for a limited-panel program than for one requiring the payer to deal with, and

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[23] *Baltimore Metropolitan Pharmaceutical Association, Inc. and Maryland Pharmacists Association*, 117 F.T.C. 95 (1994) (consent order).

[24] *Southeast Colorado Pharmacal Association*, 116 F.T.C. 51 (1993) (consent order).

[25] *See Improving Health Care, supra* note 12, at Chapter 7, p. 12.

[26] *See, e.g.*, discussion in Letter from FTC staff to Patrick C. Lynch, Attorney General, and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations (Apr. 8, 2004), at notes 10-12 and accompanying text, *available at* http://www.ftc.gov/os/2004/04/ribills.pdf.

make payments to, all of the pharmacies doing business in a program's service area.[27] Collective bargaining can undercut such competitive efficiencies. To the extent that public payers or the private market demand a certain number and distribution of pharmacies, a health plan or PBM must accede to higher collective fee demands or it will not have a pharmacy network to offer.[28] At the end of the day, unless a health plan can assemble a network of pharmacies willing to contract with the plan, and attractive to consumers and employers, the plan will have nothing to sell in the marketplace.

Increases in unit prices paid to pharmacies are not the only reason that drug costs may increase. The exemption would also permit boycotts by pharmacies to obstruct purchaser cost containment strategies. For example, PBMs typically use formularies to create price competition among drug manufacturers, and many use financial incentives to encourage patients with chronic conditions who require repeated refills of their medications to use lower cost mail order pharmacies. Such cost control programs have been shown to yield significant savings.[29] If some

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[27] *Id.*

[28] The Medicare Part D drug program, for example, requires that a Part D plan sponsor submit a network that includes enough pharmacies to provide potential beneficiaries with "convenient access" to at least one pharmacy. Requirements vary depending on whether beneficiaries are urban, suburban, or rural. In rural areas, at least 70 percent of beneficiaries in a program must be within 15 miles of a network pharmacy. *See* Access to Covered Part D Drugs, 42 C.F.R. § 423.120 (2005), *available at* http://a257.g.akamaitech.net/7/257/2422/09nov20051500/edocket.access.gpo.gov/cfr_2005/octqtr/pdf/42cfr423.120.pdf.

[29] For example, programs to encourage the use of mail-order provision of maintenance drugs alone can offer substantial savings. According to a Maryland report, greater use of mail-order maintenance drugs, as would be enabled by liberalizing Maryland insurance law, would save Maryland consumers 2-6%, and third-party carriers 5-10%, on retail drug purchases *overall*. *See* Md. Health Care Comm. and Md. Ins. Admin., *Mail-Order Purchase of Maintenance Drugs: Impact on Consumers, Payers, and Retail Pharmacies*, 2-3 (Dec. 23, 2005).

of the cost saving strategies used by health plans to control costs for prescription drugs are curtailed as a result of the collective bargaining the bill would authorize – and some are extremely unpopular with independent pharmacies – these already sizable and rapidly increasing expenditures can be expected to increase significantly. Drug expenditures in the United States in 2005 were roughly $200 billion, which represented about ten percent of total health care spending.[30] Impeding cost control strategies could significantly increase the continued growth of these expenditures.[31]

What may be uncertain about the exemption's effect is the magnitude of the increase in drug costs, which may be different in different geographic areas depending on market conditions, as well as the degree to which such increased costs would be passed on to consumers and others who pay for prescription drugs. Although it is sometimes suggested that any fee increases imposed on health plans would not be passed on to consumers, but would simply reduce health plan profits, economic theory teaches that a significant industry-wide increase in input costs can

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This is consistent with the FTC's PBM Study, which found that mail-order pharmacies typically are less expensive than retail pharmacies, even after controlling for prescription size and drug selection. *See supra* note 13 at 25. *See also* General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* at 11 (Jan. 2003) ("GAO Report"), *available at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196 (reporting that PBMs negotiate substantial discounts with retail pharmacies, but achieve greater savings using mail-order pharmacies, with an average mail-order price "about 27 percent and 53 percent below the average cash price customers would pay at a retail pharmacy for the selected brand name and generic drugs, respectively"), GAO Report at 8.

[30] *See* Aaron Catlin, et al., *National Health Spending in 2005*, 26 Health Affairs 142, 143 (Jan./Feb. 2007).

[31] *See id.* at 143 (statistics on growth of categories of health care expenditures, including prescription drugs).

be expected to raise the price of the final product.[32] And, as noted above, past enforcement actions provide numerous examples in which health care professionals' collective demands for higher fees resulted in higher costs to government purchasers.

As a major purchaser of prescription drugs, the federal government could bear significant additional costs from conduct the bill would authorize. Although the bill contains an exclusion for certain federal programs from the bill, such as the State Children's Health Insurance Program (SCHIP), and the Federal Employees Health Benefits Program (FEHBP), it expressly includes the Medicare program. Moreover, the Congressional Budget Office evaluation of the 2000 bill to immunize collective bargaining by health care professionals determined that, despite carve-outs of certain federal programs, the legislation would nonetheless significantly increase direct spending for those programs because: (1) private plans administer government benefit programs and often do not separate private and federal programs in their provider contracts; (2) higher private compensation rates would increase the market price for services, which could affect the rates that plans serving federal programs would have to pay in order to secure providers; and

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[32] Health care researchers have found that, while health care costs and health insurance premiums do not necessarily increase at identical rates on a year-to-year basis, over time "the dominant influence on premiums is underlying costs" of health care products and services. Ginsberg & Gabel, "Tracking Health Care Costs: What's New in 1998," 17:5 Health Affairs 141, 145 (Sept./Oct. 1998). In its analysis of the 2000 bill immunizing collective negotiations by health care professionals, the Congressional Budget Office projected that price increases paid by private health plans would increase direct spending by federal programs. *See* Congressional Budget Office Cost Estimate on H.R. 1304, "Quality Health Care Coalition Act of 2000" (May 17, 2000) at 5-6, *available at* http://www.cbo.gov/showdoc.cfm?index=2047&sequence=0.

(3) negotiated relaxation of utilization controls would likely raise community standards for use of certain services, which plans serving federal programs would be pressured to meet.[33]

State and local governments could incur higher costs as well, both in drug benefits for their employees and in public assistance programs. As noted above, such plans have been the victims of coercive boycotts in the past. Absent antitrust enforcement, they are likely to face them again.

Finally, making prescription drug coverage more costly means some individuals may have to do without needed drugs. Fewer employers may offer health plans incorporating prescription drug coverage and some presently covered individuals may have to forgo certain prescription purchases. In those cases, patients would suffer and there could be increased use of hospital emergency rooms, further increasing overall costs for health care and exacerbating pressures on hospital emergency rooms and public assistance programs.

IV. No Compelling Need Has Been Shown for the Exemption

The fundamental premise of those who seek antitrust immunity for collective negotiations by pharmacies is that health plans, and pharmacy benefits managers in particular, have superior bargaining power when contracting with independent pharmacies. An antitrust exemption, it is said by some, will "level the playing field" by enabling pharmacies to exercise countervailing power. According to proponents, allowing pharmacies to exercise leverage to obtain more favorable contracts will help ensure the survival of small pharmacies, and thereby promote high quality and accessible health care. This type of rationale just as easily could be applied to justify

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[33] *See* Congressional Budget Office Study, *supra* n. 32 at 5-6.

special treatment for a host of situations and participants throughout our economy, both within and outside the health care sector.

To begin with, much joint conduct by health care providers can benefit consumers, create efficiencies, and be pro-competitive, without running afoul of the antitrust laws. For example, joint ventures among pharmacists to provide medication counseling and disease management programs for patients with chronic illnesses such as asthma, diabetes, and heart disease have the potential to improve care and reduce overall costs. Commission staff has issued advisory opinions to groups of pharmacies that planned to develop such programs and jointly negotiate the fees for such services with third-party payers, finding that the antitrust laws presented no barrier to their proposed arrangements.[34] Similarly, independent pharmacies often participate in joint purchasing groups that allow them to lower costs and compete more effectively.[35] However, the proposed exemption would blunt incentives for pharmacies to undertake such lawful,

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[34] Letter to Paul E. Levenson regarding *Northeast Pharmacy Service Corporation* (July 27, 2000) (network of independent pharmacies in Massachusetts and Connecticut offering package of medication-related patient care services to physician groups) (http://www.ftc.gov/bc/adops/neletfi5.htm); Letter to John A. Cronin, Pharm. D., J.D. regarding *Orange Pharmacy Equitable Network* (May 19, 1999) (network of retail pharmacies and pharmacists offering drug product distribution and disease management services) (http://www.ftc.gov/bc/adops/openadop.htm); Letter to Allen Nichol, Pharm. D. regarding *New Jersey Pharmacists Association* (August 12, 1997) (pharmacist network offering health education and monitoring services to diabetes and asthma patients) (http://www.ftc.gov/os/1997/08/newjerad.htm).

[35] For example, the Independent Pharmacy Cooperative (IPC), which describes itself as "the nation's largest group purchasing organization for independent pharmacies," is a member-owned cooperative that has been in operation since 1984. IPC claims to represent 3200 primary and 2500 affiliate pharmacy members, whose annual purchases exceed $8 billion. *See* http://www.ipcrx.com/public/thecooperative.aspx. Another independent pharmacy purchasing cooperative, EPIC Pharmacies, Inc., was formed in 1982, and describes itself as "a not-for-profit buying group of hundreds of independently owned pharmacies across the country." *See* http://www.epicrx.com/about/index.aspx.

pro-competitive, but perhaps less easy, collaborations in order to improve service and compete more effectively in the marketplace. Moreover, the bill would not guarantee that the benefits to pharmacies of such collective action would be used to help "ensure and foster continued patient safety and quality of care," the bill's stated purpose.

Antitrust law, and the enforcement agencies, recognize the risks of undue power on the part of buyers. Excessive buying power, known as "monopsony,"[36] enables buyers to depress prices below competitive levels. In response, sellers may reduce sales or stop selling altogether, ultimately leading to higher consumer prices, lower quality, or substitution of less efficient alternative products. It is important, however, to distiuguish between this type of buyer power, which can harm competition and consumers, and disparities in bargainiug power, which are common throughout the economy and can result in lower input costs and lower prices for consumers.

The FTC is mindful of the potential harm from aggregations of market power by purchasers in the health care sector. In 2004, the FTC conducted a thorough investigation of Caremark Rx's acquisition of Advance PCS, two large national PBM firms. As part of its analysis, the agency carefully considered whether the proposed acquisition would be likely to create monopsony power with regard to PBM negotiations with retail pharmacies and ultimately determined it would not.[37] For its part, under the clearance arrangement between the two enforcement agencies, the Department of Justice has investigated various mergers of health plans

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[36] Or "oligopsony," when it results from the combination of more than one buyer.

[37] *See* Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./AdvancePCS,* File No. 031 0239 (Feb, 11, 2004).

and has taken enforcement action where it found that the transaction was likely to lead to the exercise of market power in the purchase of physician services.[38]

It appears that the concerns of retail pharmacies center on inequalities in bargaining power, rather than actual buyer market power. But even if there were evidence that health plans or PBMs were able to exercise such power over pharmacies, the Commission believes that the solution is not to authorize private competitors to use countervailing power, especially in ways that are likely to hurt consumers. Antitrust enforcement is designed to attack market power problems when and where they arise, and protecting competition in the health care sector remains a major focus of the Commission.

Proponents of antitrust exemptions in health care sometimes claim that the McCarran-Ferguson Act gives insurance companies leverage in bargaining with health care professionals. This is simply not the case. Although that Act protects certain types of activities by insurers (to the extent that such activity is regulated by state law), it has been clear for nearly thirty years that McCarran-Ferguson provides no antitrust immunity for an insurance company's agreements with providers on what they will be paid.[39] Collusion among insurers regarding the terms of such agreements would not be protected from antitrust challenge.

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[38] *See, e.g., United States v. United Health Group, Inc., and Pacificare Health Systems, Inc.*, 2006 U.S. Dist. Lexis 45938 (D.D.C. 2006), *available at* http://www.usdoj.gov/atr/cases/unitedhealth.htm; *United States v. Aetna, Inc, and The Prudential Insurance Company of America*, 1999 U.S. Dist. Lexis 19691 (D. Tex. 1999), *available at* http://www.usdoj.gov/atr/cases/indx142.htm.

[39] *Group Life and Health Insurance Co. v. Royal Drug Co.*, 440 U.S. 205 (1979); *see also Union Labor Life Ins. Co. v. Pireno*, 458 U.S. 119 (1982).

Moreover, as for concerns about disparities in bargaining power in pharmacies' negotiations with health plans or PBMs, it is important to remember that PBMs may help keep pharmacy benefit programs affordable for consumers. It also bears emphasis that there are a variety of lawful ways – short of price fixing and coercive boycotts – that pharmacies can collectively express their concerns about both price and quality issues relating to managed drug benefit programs. In their joint *Statements of Antitrust Enforcement Policy in Health Care*, the antitrust agencies have expressly recognized the potential competitive benefits of joint action by health care professionals to provide information and views to health plans about such matters.[40] Nor does antitrust law prevent pharmacies from engaging in collective advocacy before legislatures and regulatory bodies, or presenting issues to the media and the public concerning reimbursement policies and procedures of third-party payers.[41]

Lawmakers are understandably concerned that some independent pharmacies may be unable to survive in the current environment, and especially about the prospect that some rural communities might be left without a local pharmacy. But these concerns do not justify a broad antitrust exemption that would apply to diverse businesses in markets throughout the country. "Independent pharmacies" under H.R. 971 include not just rural pharmacies, but urban and

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[40] *See* U.S. Department of Justice and the Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (August 1996) at Statements 4 and 5, 4 Trade Reg. Rep. (CCH) ¶ 13,153, *available at* http://www.ftc.gov/reports/hlth3s.pdf.

[41] For example, a 2003 FTC staff advisory opinion explains that the antitrust laws did not prevent physicians in Dayton, Ohio, from collecting and publicizing information about Dayton health care market conditions, including information about insurer payments, to educate the general public about the physicians' concerns about the reimbursement policies and procedures of third-party payers in Dayton. Letter from Jeffrey W. Brennan to Gregory G. Binford, (February 6, 2003), *available at* http://www.ftc.gov/bc/adops/030206dayton.shtm.

suburban ones, and not just single-store entities but multi-store chains, pharmacy franchises, and privately-owned supermarket pharmacies. To the extent that certain local concerns may warrant attention, targeted efforts to address particular issues in the distribution of pharmaceuticals and pharmacy services (perhaps looking to strategies used for medically under-served areas) may be a better way to address problems of access to prescription drugs, while avoiding the concerns that are raised by an antitrust exemption.

V. Conclusion

Antitrust enforcement in the health care sector has helped ensure that new and potentially more efficient ways of delivering and financing health care services can arise and compete in the market for acceptance by consumers. Although health care markets have changed dramatically over time, and continue to evolve, collective action by health care providers to obstruct new models for providing or paying for care, or to interfere with cost-conscious purchasing, remains a significant threat to consumers. The public is looking to policymakers to address widespread concerns about our health care system: high costs, uneven quality, and a large and increasing number of people who are uninsured. Giving health care providers – whether pharmacies, physicians, or others – a license to engage iu price fixiug and boycotts iu order to extract higher payments from third-party payers would be a costly step backward, not forward, on the path to a better health care system.

Mr. CONYERS. Thank you very, very much, Mr. Wales. Is this your personal testimony or——

Mr. WALES. The way I think it works is the written testimony was the testimony of the Commission itself. My remarks today, though, are my own.

Mr. CONYERS. Okay.

Mr. WEINER. When we ask him questions, who is he speaking for?

Mr. CONYERS. Well, it would probably depend on the question.

Mr. WALES. The questions and the answers I will give will be my own.

Mr. CONYERS. That's a little unusual arrangement, I just wanted to observe, because I didn't think I was hearing correctly. But your testimony is welcomed and appreciated.

Now we have another antitrust attorney, David Balto, and he is testifying on behalf of the National Community Pharmacists Association. He has practiced antitrust law for quite a while, and he's spent a lot of time in the Department of Justice's Antitrust Division, as well as the Federal Trade Commission. And he currently chairs the American Bar Association's Antitrust Section on Health Care Committee.

We have your testimony, and now we'd like to hear from you.

TESTIMONY OF DAVID A. BALTO, ANTITRUST ATTORNEY, ON BEHALF OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Mr. BALTO. Thank you, Chairman Conyers and Ranking Member Keller. It's a privilege today for me to come before you and testify on behalf of the independent pharmacists of the United States and the National Community Pharmacists Association.

When you look at health care antitrust issues, you should ask two questions: Who represents the consumer? And who benefits?

Who represents the consumer in the pharmaceutical distribution system? It's not the insurance companies. They're there to serve the interest of their stockholders. It's not the employers, for whom health care costs is just a line item. It's the pharmacist: the pharmacist who wakes up the 5 o'clock in the morning to go and deal with a claims problem; the pharmacist who answers a question at 10 o'clock at night; especially the community pharmacist, dedicated individuals, many of whom serve underserved areas in the United States, rural areas, low-income areas, which just simply aren't profitable for chain pharmacies.

Who profits? Well, it's the PBMs and insurance companies that are profiting. While they're making record profits, they're doing it in part by squeezing independent pharmacists to their last ounce of survival, driving them from business.

Now, you passed H.R. 1304, the Campbell-Conyers bill, back 7 years ago, because you saw it was important for the health care provider to be able to voice for itself and for the consumer to have a voice in this process. Seven years later, that imbalance you sought to redress is far worse. Both the PBM and insurance industries have become vastly more concentrated. PBMs are a type of oligopoly of three firms that basically control the market. They're making record, astronomical profits.

They're also make a record in something far less glorious: They're creating a record of consumer protection violations. The Justice Department and the Coalition of State Attorneys General have sued them over and over again to stop these anticonsumer practices. That's another reason why you want to give the independent pharmacists a voice at the bargaining table.

But let's be clear about this. The independent pharmacist is gagged. It's gagged by sound economic policy; it's gagged by an antitrust rule, the per se rule against antitrust price fixing, which says that if Mr. Dozier and Mr. James dare go and voice things together, that conduct can be illegal under the per se rule.

The PBMs are smart, and they have expensive lawyers, and they use that rule to threaten litigation against the pharmacists to prevent them from acting collectively. Will they win those cases? No. No sound court would find those as violations. But the cost of that litigation prevents the PBM pharmacies from actually being able to voice their concerns at the bargaining table.

Is an exception warranted under the law? It's clearly warranted under the facts. You want those independent pharmacists to be able to speak for you. You want them to speak for themselves. The antitrust laws are not perfect, and we don't want the antitrust laws to become the enemy of the good. Basically, what the antitrust laws have done is create a sword of Damocles, so that if the independent pharmacist voices its concerns, they can be threatened by costly antitrust litigation.

If you look at past precedents of the Congress, you'll see that they've acted to create exemptions when the antitrust law prevents this type of pro-competitive conduct or creates the need to create countervailing power, such as the Capper-Volstead Act exemption.

Let me close with one last point. Will this be harmful? Not on your life. Several months ago, the FTC investigated Rite Aid's acquisition of records, which gave it more than a 40 percent market share in many metropolitan markets in upstate New York. They inquired, could Rite Aid use that 40 percent market power to get a better deal from PBMs? Could they extract super-competitive profits? The answer was no, they didn't do a thing in terms of protecting PBMs. Why? Because 40 percent didn't matter when you were dealing with PBMs.

If Mr. James or Mr. Dozier or the 20 pharmacists in Florida that Mr. Weiner talks about want to get together, they deserve that opportunity to collaborate and innovate. They deserve to have this sword of Damocles taken away from them.

Who speaks for the consumer, Mr. Chairman? The independent pharmacist speaks for the consumer. And the independent pharmacist needs this Committee and this Congress to come up and speak for them by enacting H.R. 971.

Thank you.

[The prepared statement of Mr. Balto follows:]

PREPARED STATEMENT OF DAVID A. BALTO

Testimony of David A. Balto

Before the Antitrust Taskforce of the House Judiciary Committee

The Impact of Our Antitrust Laws on Community Pharmacies and Their Patients

Thursday, October 18, 2007

I appreciate the privilege of testifying before you today about the impact of our antitrust laws on independent community pharmacies and their patients. As I explain in my testimony, H.R. 971, the Community Pharmacies Fairness Act of 2007, is a necessary and appropriate response to a severe imbalance in the pharmaceutical distribution network. While Pharmacy Benefit Managers (PBMs) make record profits, independent pharmacies are driven from the market and consumers are suffering from anticompetitive and deceptive PBM practices. Efforts by independent pharmacies to collaborate to redress this imbalance or protect consumers are quashed by the threat of antitrust litigation. This legislation is a prudent response to this significant market imbalance and its enactment will benefit both consumers and competition.

I have practiced antitrust law for over twenty years, primarily as a public servant in the Antitrust Division of the Department of Justice and the

Federal Trade Commission.[1] At the FTC in the 1990s, I was attorney advisor to Chairman Robert Pitofsky and led the Policy Office of the Bureau of Competition.[2]

It is important that the Task Force is holding this Hearing on the impact of the antitrust laws on independent pharmacies. Independent pharmacies are a critical component to the delivery of drugs throughout the United States. They serve numerous underserved rural, inner-city and urban areas. Because of the face-to-face relationship with their local independent pharmacist, patients are more likely to take their medicines on-time, more likely to take them properly, more likely to refill meds before they run out and more likely to avoid harmful drug interactions. Patient access to the thousands of independent pharmacies helps to lower health care costs by promoting patient health every day.

My testimony makes the following points:

- The pharmaceutical distribution market is broken. PBMs engage in a wide range of anticonsumer and fraudulent practices. There is a significant disparity in power between PBMs and independent pharmacies and PBMs exploit that disparity by forcing "take it or

[1] In the past I have represented both chain and independent pharmacies, pharmacy benefit managers, insurance companies, and employers who have purchased PBM services. I testified on behalf of the State of Maine in *PCMA v. Maine* a case involving a Maine statute regulating PBMs. I also regularly represent consumer advocacy groups, such as the Consumer Federation of America, Consumers Union, U.S. PIRG and Families USA. A list of my recent public interest advocacy is listed in Appendix A.

[2] I have written numerous articles on healthcare and pharmaceutical antitrust, including what is considered one the seminal articles on collaboration by pharmacies. David A. Balto, "Cooperating to Compete: Antitrust Analysis of Healthcare Joint Ventures," 32 *Saint Louis University Law Journal* 191 (1998).

leave it" deals on independent pharmacies and preventing pharmacies from advocating on behalf of consumers;

- Collective negotiation by independent pharmacies is a necessary response to this disparity;
- Consumers suffer if independent pharmacies cannot collectively negotiate;
- The threat of antitrust liability prevents collective negotiation;
- An antitrust exemption to permit collective negotiation is appropriate and consistent with past Congressional actions; and
- Anticompetitive effects from an antitrust exemption are highly unlikely because independent pharmacies are too small to have market power.

I. The Broken Market of Pharmaceutical Distribution

Seven years ago, Congress considered, and the House of Representatives passed the Health Care Quality Coalition Act, H.R. 1304, a bill co-sponsored by Congressmen Campbell and Conyers (and 220 other members). Part of the reason for the Act was the significant imbalance in the market between large insurers and healthcare providers and the belief that collective negotiation would and "will create a more equal balance of negotiating power, will promote competition and will enhance the quality of patient care."

These concerns are now even greater seven years later. Both the health insurance and PBM markets have become significantly more concentrated as continual consolidation has gone unabated by antitrust enforcement. The top three PBMs have become industry giants with almost

$2 billion in annual revenue. At the same time independent pharmacies have average sales below $3.5 million annually and these entrepreneurs are increasingly being driven out of the market by anticompetitive and coercive PBM tactics.

Over the past seven years there have been over a score of PBM acquisitions that have led to three firms – Express Scripts, CVS/Caremark, and Medco—dominating the market. None of these acquisitions have been challenged by the FTC. In fact, the merger that eliminated the fourth largest firm, (Caremark's acquisition of Advance PCS) was resolved based on merely a "quick look" review and CVS' subsequent acquisition of Caremark was completed without a Second Request for additional information.[3] These three firms now have over 200 million covered lives and are significantly larger than any of their rivals.[4] Simply no pharmacy, whether independent or chain, can survive without serving the major PBMs. Not surprisingly the result has been higher costs for the buyers of PBM services, substantially reduced fees for independent pharmacies and higher co-pays for consumers.

[3] The law firm that represented one of the parties in the Caremark/AdvancePCS merger observed that the investigation was closed on a "quick look" review. *See* http://www.jonesday.com/experience/experience_detail.aspx?exID=S9298. This means that the Commission did not conduct a full investigation of that merger.

[4] A description of the competitive problems in the PBM market and the exercise of market power by PBMs is contained in a recent white paper to the FTC. "Express Script's Proposed Acquisition of Caremark: An Antitrust White Paper," Sept. 6, 2006. http://www.antitrustinstitute.org/archives/files/AAI_Express%20Scripts_Caremark_2-14_021520071110.pdf

The PBM market has become a tight oligopoly and the results are predictable. The Wall Street Journal recently observed that healthcare networks have not functioned effectively and middlemen (especially PBMs) often exercise market power to the detriment of consumers:

> [W]hile the Internet, deregulation and relentless corporate cost-cutting have squeezed middlemen elsewhere, the health-care middlemen are prospering. **The three largest pharmaceutical benefit managers, for instance, had net income of $1.9 billion last year, a sum that exceeds the annual operating budget of New York's Sloan Kettering cancer center**. In corners of the system such as Medicaid managed care and nursing-home drugs, little-known intermediaries rack up tens or hundreds of millions of dollars in profit.[5]

PBMs have used their power to drive independent pharmacies out of business or close to their breaking point. PBMs have consistently driven reimbursement rates down, even though they often deceive the plan sponsors as to the actual dispensing rates.[6] Almost all PBMs own mail order operations and they seek to drive consumers to more highly profitable mail order distribution and away from independent pharmacies that offer the level of quality, advice and personal service consumers prefer. Unfortunately, consumers often suffer from the conversion to mail order: they are given little choice, there is a greater chance of adverse reactions, and there is little

[5] Barbara Martinez, et al., "Health-Care Goldmines: Middlemen Strike it Rich," *Wall Street Journal*, A1 (December 29, 2006).

[6] Many of the deception and fraud cases brought against PBMs allege that they have "played the spread" suggesting to plan sponsors that they provide a higher dispensing rate than actually paid to pharmacies.

if any consumer service. Any consumer who has spent hours on the phone waiting for an answer on a mail order prescription sees little "efficiency" from driving independent pharmacies from the market.

Moreover, the PBM industry has been plagued with precedent-setting enforcement actions, and substantial allegations of fraudulent, deceptive, and anticompetitive conduct. As a bipartisan group of state legislators has noted:

> We know of no other market in which there has been such a significant number of prominent enforcement actions and investigations, especially in a market with such a significant impact on taxpayers. Simply put, throughout the United States, numerous states are devoting considerable enforcement resources to combating fraudulent and anticompetitive conduct by PBMs. This is because those activities are taking millions of taxpayer dollars and denying government buyers the opportunity to drive the best bargain for the state.[7]

In the past three years alone, cases brought by the U.S. Department of Justice (DOJ) and State Attorneys Generals (AGs) have secured over $300 million in penalties and fines for deceptive and fraudulent conduct by the major PBMs.[8] Several investigations of the three major PBMs continue by a group of AGs and the DOJ. The current concentrated nature of the national PBM market has exacerbated these problems and has increased the need for

[7] Letter from Senator Mark Montigny to FTC Chairman Deborah Platt Majoras (May 11, 2005).
[8] A description of these enforcement actions and other cases challenging anticompetitive and fraudulent conduct by PBMs is contained at Appendix B.

both government enforcement and potential regulatory oversight of the PBM industry. [9]

II. Collective Negotiation by Pharmacies is Necessary Response to a Broken Market

No one testifying today can dispute that there is a significant bargaining imbalance between PBMs on the one hand and independent pharmacies on the other hand. PBMs and insurance companies have tremendous power in the market because of their size and their concentration in the market. This power is typically called *monopsony* or *oligopsony* power. With this power, PBMs, either individually or collectively, are able to drive compensation below competitive levels.[10] The result is that independent pharmacies have been driven out of business at a rapid rate, thereby reducing consumer choice, increasing waiting times, and increasing quality-adjusted prices for consumers.[11] Consumers who prefer the level of personal service they receive at their independent pharmacy suffer. The

[9] These practices are similar to those identified by Chairman Conyers as the reason for enactment of H.R. 1304 an earlier immunity bill: "The dangers posed by the ever-increasing market concentration are exacerbated by the practice of health insurers engaging in rather heavy handed negotiating tactics, in some instances requiring exclusionary contractual commitments from health care providers. These restrictive terms are frequently offered on a take-it-or leave it basis under the threat of the loss of the provider's patients or exclusion from access to their patients." Hearings Transcript at 5.

[10] As Judge Hopkins in an antitrust case brought against PBMs has observed, "By conspiring to hold down prices paid to independent pharmacies (among other alleged action), PBMs would bankrupt those pharmacies, thereby capturing a larger segment of the insurance paid prescription market for the PBM's own prescription dispensing business and allowing the PBMs to charge higher prices for that service." (*N. Jackson Pharm., Inc. v. Express Scripts, Inc.*, 345 F. Supp. 2d 1279, 1292)

[11] These are particularly serious concerns for rural consumers. Over 58% of independent pharmacies are located in an area with a population of less than 20,000.

individual care and attention these pharmacists provide may become of relic of the past due to the anticompetitive conduct of the major PBMs.

Moreover, there is a second imbalance in the market. Independent pharmacies compete against much larger chain pharmacies, with billions of dollars of sales, thousands of stores and their own mail order operations. Many chains such as CVS and Walgreens own their own PBMs. As such the chain pharmacies have a superior bargaining position than independent pharmacies. As described below, independent pharmacies cannot secure a similar position because the threat of antitrust liability prevents them from jointly bargaining. Thus, the threat of antitrust litigation currently places independent pharmacies at a significant competitive disadvantage to chain pharmacies, and as a result, patients and customers are suffering.

The inability of independent pharmacies to jointly negotiate also prevents them from advocating for consumers with the PBMs on the fraudulent and deceptive practices that have led to the numerous enforcement actions described above. Because PBMs have oligopolistic power, they are able to force a "contract of adhesion" on independent pharmacies. The result is that independent pharmacies have little choice but to accept one-sided, non-negotiable service agreements, often contracts with provisions that harm consumers. Some of the practices include:

- preventing independent pharmacies from dispensing 90 days of medication;
- impeding independent pharmacies from adequately counseling their patients;
- requiring "all product clauses" that require pharmacies to participate in all plans of a PBM, even at an adverse reimbursement rate;
- preventing pharmacies from informing consumers of less expensive and more appropriate prescriptions; and
- forcing onerous contract requirements and significant contract penalties.

PBMs may assert they are simply trying to derive the best bargain for their "customers"--the "plan sponsors"--that buy PBM services.[12] But PBMs do not engage in these practices simply because they are trying to derive the best bargain. PBMs have their own mail-order operations, which are typically far more profitable to the PBM than dispensing through independent pharmacies. Thus, it is in the PBM's interest to drive independent pharmacies from the market, and to compel consumers to use mail-order distribution where they make significant profits by increasing the volume of transactions they conduct through this method and the rebates from drug manufacturers.

III. Consumers Suffer When Pharmacies cannot Negotiate

In this larger battle to control healthcare costs, the question often arises: Who will speak for the consumer? As I articulated in recent

[12] A plan sponsor is the employer, union, or insurance company that purchases the PBM services.

testimony to the Nevada Insurance Commissioner on the United Healthcare/Sierra merger, perhaps the party in the best position to advocate for consumers in a managed care environment is the healthcare provider itself.[13] The healthcare provider is the sole actor who has a face-to-face relationship with the healthcare consumer. Actions by managed care entities reduce the quality of care directly and also negatively impact the healthcare provider. Moreover, the healthcare provider, because of their ethical obligations as a healthcare professional, has a responsibility to not only protect the interest of the consumer but also to provide a high quality of care. Insurance companies and PBMs directly interfere with the ability of the healthcare provider to fulfill this obligation.

When healthcare providers (including pharmacies) are essentially forced to accept a "take it or leave it offer," both the provider and the consumer suffer. The insurers and PBMs can reduce compensation to such a level that the healthcare provider has to increase volume, reduce the level of service, increase waiting times, and reduce staff or close its business. Moreover, this take-it-or-leave-it environment healthcare providers from

[13] Testimony of David Balto on behalf of the American Antitrust Institute and Consumer Federation of America Before the Nevada Commissioner of Insurance on the United Health Group Proposed Acquisition of Sierra Health Services, July 27, 2007.

being able to expand, innovate, and provide new services.[14] In the pharmacy environment the PBM's unbridled power prevents independent pharmacies from increasing staffing, and adding additional services such as blood pressure, cholesterol, or lipid screening, or ongoing counseling programs.

Enabling independent pharmacies to negotiate will allow the pharmacist to serve as advocate for the consumer, addressing some of the anticonsumer conduct addressed above. Some of the issues a pharmacy collaboration could negotiate over include:

- the level of disclosure to consumers (especially of copay requirements),
- dispensing 90-day prescriptions,
- limitations on formularies that restrict patient treatment options;
- onerous pre-authorization requirements; and
- and adequate notice and approval of drug switches.

IV. The Threat of Potential Antitrust Liability Prevents Independent Pharmacies from Collaborating

As you well know, the antitrust laws provide relatively few bright line proscriptions on conduct. Although this can be beneficial, as it enables the law to evolve as markets evolve, it can also be harmful to the extent that antitrust uncertainly prevents efficient or competitively neutral conduct. Antitrust law imposes potentially severe penalties for violation: treble damages, attorneys fees, and costs. In addition, the cost and time of antitrust

[14] *See United States v. Aetna*, Revised Complaint Impact Statement, Civil Action 3-99CV1398-H (N.D.Tex, 1999).

litigation can be extremely burdensome. Thus, the mere threat of antitrust litigation can often prevent procompetitive or competitively neutral conduct.

Unfortunately PBMs, with their substantial resources, are more than ready to exploit antitrust uncertainty and use the threat of antitrust litigation to stifle collaboration by independent pharmacies. When these pharmacies make any material attempt to collaborate or collectively negotiate, they are met with an all-too willing antitrust litigation adversary. In those cases, independent pharmacies face the threat of treble damage liability as well as the costs of exhaustive discovery.[15] In effect, pharmacies are "gagged" at the bargaining table by this threat of antitrust litigation.

Moreover, because of uncertainty in the law the PBMs can allege that these arrangements are per se illegal, rather than illegal under the rule of reason. That means that a PBM plaintiff need not demonstrate that some pharmacy collaboration actually harmed competition or led to higher prices. Under the per se rule a collaboration between two small pharmacies could face antitrust liability, even though it is indisputable that it could not cause anticompetitive harm.

[15] A good example of this is the antitrust suit brought by Merck-Medco against an alliance of independent pharmacies in Maryland in the mid-1990s. Although the case was ultimately dismissed because the Court held "no genuine issue … existed on the issue…that the defendants conspired to boycott," the litigation took over three years and cost millions of dollars to defend.

I would expect some to suggest that pharmacies could receive approval for collaborations under the Healthcare Policy Statements, but I would not consider that to be a viable option. History has shown the limited avenue for approval under the Health Care Policy Statements. The process and cost of approval can be daunting. It can take several months and cost the providers considerable legal fees. Not surprisingly only physician groups consisting of hundred of providers have been able to survive this process and the FTC has cleared less than a handful of these arrangements in the past seven years. Independent pharmacies simply lack the resources to survive this time-consuming and expensive process.[16]

The question being evaluated by the agencies in these matters is not whether the collaboration can be competitively harmful. Rather, the question is simply whether the collaboration is per se illegal. Thus, under the agencies' approach, collaboration even by a small group of providers can be condemned even if there is indisputably no likelihood of any adverse impact on consumers.

V. An Antitrust Exemption is Appropriate

Antitrust exemptions and immunities are not favored by antitrust enforcers. Sometimes antitrust exemptions can be used to create market

[16] In addition, even if an entity can secure a staff advisory opinion under the Policy Statements, that opinion does not prevent later private litigation.

power or prevent the forces of competition from working. A good example of this is the McCarran-Ferguson Act which provides broad immunity to insurance companies. This is an exemption that has clearly outlived its utility.

On the other hand, in other cases limited antitrust exemptions may serve important social, political, or competition goals. The antitrust laws are not perfect. Congress has recognized on several occasions the need to provide exceptions to the antitrust laws for a wide variety of reasons. Sometimes Congress has enacted exemptions to protect the interests of individuals and firms who need some degree of countervailing power to assure a competitive market. In other cases Congress has acted prudently to afford firms antitrust exemptions when antitrust liability (or the threat of antitrust liability) prevented conduct which ultimately benefited consumers. The proposed legislation is consistent with both of these objectives.

Countervailing power

As discussed above, permitting pharmacy collaboration will fulfill numerous procompetitive and proconsumer goals. Creating countervailing power that may curb the monopsony or oligopsony power of PBMs will ultimately benefit consumers and independent pharmacies. With greater power at the bargaining table independent pharmacies can negotiate for

better terms, more disclosure and greater choice. Congress has acted to permit small firms to create some level of countervailing power. For example, the Capper-Volstead Act protects the ability of small farmers to form agricultural cooperatives to sell their products collectively.[17] Absent the Capper-Volstead Act, large agricultural processors could exercise their monopsony power and drive numerous farmers out of business. H.R. 971, in a similar fashion, redresses the bargaining imbalances between independent pharmacies and PBMs.[18]

Resolving antitrust uncertainties to protect procompetitive conduct

The antitrust laws, of course, are elastic. And as such, these laws are often interpreted in ways that deter competitive conduct. In some cases, the mere threat of the potential liability, cost and time of antitrust litigation deters market participants from engaging in collaborative conduct which could ultimately benefit competition and consumers. Congress has acted on a number of occasions to protect the interests of rivals to engage in conduct that may prospectively be procompetitive. Such exemptions include the National Cooperative Production Research Act, the Standards Development

[17] 7 U.S.C. § 291.

[18] The benefits of facilitating countervailing power by granting an antitrust immunity are discussed in "Antitrust Immunities and Exemptions", prepared for the December 1, 2005 Hearing of the Antitrust Modernization Commission by Professor Peter C. Carstensen.

Organization Advancement Act, the Charitable Donation Antitrust Immunity Act, and the Medical Resident Matching Program Act.

As discussed earlier, the threat of antitrust litigation deters procompetitive collaboration among independent pharmacists. Some might suggest that antitrust uncertainty is simply the cost of doing business that most businesses have to shoulder. Congress clearly has not accepted that notion. By enacting the Standards Development Organizations Advancement Act, Congress was protecting the interests of prosperous high tech firms such as Dell, Intel and Hewlett Packard. If these large companies needed protection from antitrust litigation aren't independent pharmacies even more vulnerable and thus also deserving of protection?

VI. There is no Likelihood of Anticompetitive Effect from the Legislation

One can expect that the opponents of the legislation will suggest anticompetitive results from permitting independent pharmacies to negotiate. They will suggest that pharmacists will be able to secure market power by collaborating and use that market power to charge PBMs supracompetitive prices for access to their pharmacies. Such arguments are clearly unsupported by the facts.

On occasion, the FTC has recognized the potential for chain pharmacies to raise prices to PBMs by acquiring market power through

mergers. In the mid-1990s, for example, the FTC challenged the merger of Rite Aid and Revco because it would have given the merged firm the ability to raise the rate of compensation to PBMs.

More recently, the FTC appears to have found that these concerns over the exercise of market power by chain pharmacies over the PBMs have diminished. In its evaluation of Rite Aid's acquisition of Eckerd, the third and fourth largest pharmacy chains in the U.S., the FTC carefully evaluated the impact on several geographic markets. Even though the merged firm's post-merger market share exceeded 40% in numerous upstate New York metropolitan markets, the FTC did not seek relief in any of those markets. Nor did they seek relief to protect PBMs from the exercise of market power by the merged firm. The FTC did require the divestiture of over 20 stores in numerous markets to protect "cash paying customers," those without insurance coverage, but again they found it unnecessary to protect the PBMs.

The FTC's action in the Rite Aid merger suggests that in the context of pharmacies exercising market power against PBMs a market share substantially above 40% is necessary to pose a competitive threat. It seems highly unlikely that there are many markets where independent pharmacies exceed a 40% market share. Moreover, it seems unlikely that any

collaboration would necessarily include all independent pharmacies. It seems highly dubious that any independent pharmacy collaboration could be large enough to turn the tables and extract supracompetitive prices from powerful PBMs.

VII. The Reasons to Oppose Collective Negotiation are even less persuasive than they were in 2000

As you know, this Committee and the House of Representatives passed the Healthcare Quality Improvements Act of 2000. That Act provided the same antitrust exemptions as H.R. 971 for all healthcare providers, including doctors, dentists, and other types of healthcare professionals. When the bill was proposed there was a well-funded and well-organized opposition by insurance groups. The opposition to the bill consisted of basically two arguments. First, legislation was unnecessary because collective negotiation could be permissible under the DOJ/FTC Healthcare Policy Statements. Second, if there was a problem with the bargaining imbalance, the answer was stronger enforcement against health insurer and PBM anticompetitive conduct and mergers. Yet in both respects, history has proven the arguments of the opponents to the legislation wrong.

As to collective negotiation, in the seven years since the legislation was passed, the FTC has approved less than a handful of physician-based joint ventures. The physician-based joint ventures that were approved, came

only after extensive investigations that cost those physician groups (which were very large physician groups) hundreds of thousands of dollars.

As to the suggestion that the proper response to anticompetitive behavior was to attack anticompetitive mergers or anticompetitive practices, the Antitrust Division and the FTC have simply not stepped up to the plate. In the past seven years, the Division and the FTC have brought no cases against anticompetitive conduct by insurance companies or PBMs, even though state enforcement officials and private plaintiffs have brought numerous actions. Moreover, the FTC has not challenged any PBM merger, and the Antitrust Division has challenged just a single insurance merger. Not surprisingly, in the last seven years both the PBM and the insurance markets have become far more concentrated. To the extent that this Committee and the House of Representatives recognized the need for this legislation in 2000, that need is far more substantial today.

VIII. Conclusion

The pharmaceutical distribution system has significant problems. Consumers value the work of their pharmacist more than any other participant in the distribution system. PBMs have a level of market power so substantial that they can effectively coerce independent pharmacies into arrangements that keep them barely viable. Through the threat of antitrust

litigation, PBMs can effectively gag pharmacies from advocating on behalf of consumers, and from helping to prevent anticompetitive practices by PBMs. H.R. 971 should be enacted to eliminate this antitrust uncertainty and allow independent pharmacies to fully participate in the marketplace.

Appendix A: Public Interest Advocacy

- Testimony before the Antitrust Subcommittee of the Senate Judiciary Committee on the competitive impact of the XM/Sirius Merger. (Mar. 20, 2007)

- Advocacy on behalf of the American Antitrust Institute in opposition to the Express Scripts/Caremark merger. (white paper to FTC, Feb. 2007)

- Testimony on behalf of the American Antitrust Institute, Consumer Federation of America and Consumers for Healthcare Choices before the Nevada Commissioner of Insurance in opposition to United Healthcare's acquisition of Sierra. (July 27, 2007)

- Advocacy on behalf of the National Black Farmers Alliance in opposition to the Monsanto/Delta Pine merger. (Mar. 2007)

- Advocacy on behalf of the Organization for Competitive Markets, the National Farmers Union, and the UFCW in opposition to the Premium Standard/Smithfield merger (Sept. 2006)

- Advocacy on behalf of several consumer groups in opposition to SCI/Alderwoods merger. (May 2006)

- Advocacy on behalf of the Consumers Union, Consumer Federation of America, and U.S. PIRG in opposition to the FTC's proposed Consent Order against Kmart for deceptive marketing of gift cards. (Apr. 2007)

- Testimony before the State Legislature of Texas on PBM reform legislation. (Nov. 2006)

- Testimony before the State Legislature of Vermont on PBM reform legislation. (Apr. 2007)

- Testimony before the State Legislature of Iowa on PBM reform legislation. (Mar. 2006)

- Testimony before the State Legislature of Arkansas on PBM reform legislation. (Feb. 2006)

- Testimony before the City Council of the District of Columbia on PBM reform legislation. (Jun. 2006)

- Amicus brief on behalf of the American Antitrust Institute and Consumer Federation of America in *Broadcom v. Qualcomm* (Third Cir., Dec. 2006).

- Amicus brief on behalf of American Antitrust Institute and Consumer Federation of America in *McKenzie v. Peace Health* (Ninth Cir., Mar. 2007).

- Amicus brief on behalf of Consumer Federation of America, Consumers Union and Families USA in *DDAVP Antitrust Litigation* (Second Cir., May 2007).

- Amicus brief on behalf of American Antitrust Institute, Consumer Federation of America, and Organization for Competitive Markets in *FTC v. Whole Foods* (D.D.C., Aug. 2007).

Appendix B: PBM Litigation

Ongoing Federal and State Litigation Regarding Pharmacy Benefit Managers

David A. Balto
September 2007

I. *Qui Tam* – "Whistleblower" Lawsuits

***United States, ex rel. George Bradford Hunt and Walter W. Gauger, et al. v. Merck & Co., Inc., Merck-Medco Managed Care, L.L.C. and Medco Health Solutions, Inc.*, and *United States, ex rel. Joseph Piacentile v. Merck & Co., Inc. and Merck-Medco Managed Care, L.L.C.;Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania; Judge Anita B. Brody.* (Also cited as *United States of America v. Merck-Medco Managed Care L.L.C., et al.*)**

In these whistleblower lawsuits, complaints were filed under the federal False Claims Act and state False Claims Acts against Medco Health Solutions, Inc. ("Medco"). The cases allege that Merck and Medco systematically defrauded government-funded health insurance programs by accepting kickbacks in exchange for referring patients to certain products, secretly accepting rebates from drug manufacturers in exchange for increasing product market share, secretly increasing long-term drug costs, and failing to comply with state-mandated quality of care standards. This manner in which this was done included: (1) inducing physicians to switch patient medications (drug interchange) by providing misleading, false or incomplete information that subverted patient care to profit motives; (2) secretly increasing the cost of drugs provided to beneficiaries by knowingly interchanging patients' medications to prevent them from taking advantage of soon to be released available generic drugs; and, (3) violating basic state requirements governing pharmacist supervision of prescription drug fulfillment processes. Through such conduct the United States alleges that Merck and Medco violated their contracts with government-funded health insurance programs.

These cases were brought by the whistleblowers on behalf of the United States. The *Hunt and Gauger* amended complaint was filed on March 18, 2003. The *Piacentile* complaint was filed on February 10, 2000. On June 20, 2003, the United States intervened following an extensive investigation of the factual allegations and evidentiary support provided by the relators. This investigation was conducted by numerous federal agencies, including the U.S. Attorney's Office, the Eastern District of Pennsylvania, the Office of Inspector General of the Office of Personnel Management, the Office of Inspector General of the Department of Health and Human Services, and the Defense

Criminal Investigative Service. On December 9, 2003, the United States amended its complaint adding two executives of Medco as defendants. In the amended complaint these executives were accused caused of (1) covering up the intentional destruction of patient prescriptions, (2) destroying and directing the destruction of patient prescriptions, and (3) making misleading statements about the cover-up when questioned by the Department of Justice. The amended complaint also added a count against Medco under the Public Contract Anti-Kickback Act for making improper payments to health plans to induce them to select Medco as a pharmacy benefit manager for government contracts.

On April 26, 2004, the United States, 20 state attorneys generals, and the defendants agreed to a settlement of claims for injunctive relief and unfair trade practice laws.[19] A separate consent order was filed by the states to cover the injunctive and monetary claims. This order instructs Medco to pay $20 million to the states in damages, $6.6 million to the states in fees and costs, and about $2.5 million in restitution to patients who incurred expenses related to drug switching between a set of cholesterol controlling drugs. The consent order filed in the federal district court of the Eastern District of Pennsylvania excluded claims for damages, penalties, or restitution under federal statutes and common law.

The settlement prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the prescribed drug;
- The prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in two years within a therapeutic class of drugs for any patient.

The settlement requires Medco to:

- Disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to prescribers and patients Medco's financial incentives for certain drug switches;
- Disclose to prescribers material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health care costs and notify patients and prescribers that such reimbursement is available;
- Obtain express, verifiable authorization from the prescriber for all drug switches;
- Inform patients that they may decline the drug switch and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and

[19] The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order and call center pharmacies.

On October 23, 2006 a final settlement in this case was reached with Medco agreeing to pay $155 million. As part of the settlement agreement, Medco and the government entered into a consent decree that includes prohibitions on drug switches resulting in the dispensing of more expensive drugs or drugs without generic substitutes.

The consent decree requires Medco to:

- Disclose to prescribing physicians any material safety and efficacy differences between the switched drugs.
- Disclose to both prescribing physicians and patients the fact that it receives payments from pharmaceutical manufacturers for drug switching that do not inure to the benefit of the health plan.
- Disclose in its communications with patients and physicians the role of its Pharmacy and Therapeutics Committee in initiating, reviewing, approving or endorsing the drug switch.
- Provide a periodic accounting of payments to health plans that have contracted to receive from Medco any manufacturer payments (*e.g.*, rebates or market share incentives paid by manufacturers).
- Disclose to existing or prospective health plan clients, in advance of executing an agreement with the health plan, the fact that Medco will solicit and receive manufacturer payments and may or may not pass such payments through to the plans.

As part of the settlement, Medco and the Department of Health and Human Services Office of Inspector General entered into a corporate integrity agreement (CIA) as a condition of Medco's continued participation in government health programs. The CIA will last for a period of five years, and requires that agreements under which Medco receives payments from manufacturers (*e.g.*, rebates and market share incentives) be in writing and meet certain conditions.

United States of America, et al. v. AdvancePCS, Inc. (Case No. 02-cv-09236); U.S. District Court for the Eastern District of Pennsylvania; Judge Norma L. Shapiro.

In this whistleblower lawsuit, like the ones described above, the complaint was filed under the federal False Claims Act. The complaints, the first of which was filed in 2002 on behalf of the United States against AdvancePCS, Inc, acquired by Caremark Rx Inc. in 2004, allege the PBM knowingly solicited and received kickbacks from pharmaceutical manufacturers. These kickbacks were allegedly paid in exchange for favorable treatment of the manufacturers' products under contracts with government programs, including the Federal Employees Health Benefit Program, the Mailhandlers Health Benefit Program

and Medicare + Choice programs. The lawsuit also alleges that improper kickbacks were paid by AdvancePCS to existing and potential customers as an inducement to their signing contracts with the PBM, and that excess fees paid to AdvancePCS in connection with fee-for-service arrangements resulted in the submission of false claims. The government also incorporated in the Settlement Agreement allegations involving flat fee rebates which were allegedly received for inclusion of certain heavily utilized drugs.

This case was brought by the whistleblowers on behalf of the United States. The first complaint was filed on December 20, 2002. The first amended complaint was filed on April 11, 2003; both complaints filed under seal. On September 8, 2005, AdvancePCS, Inc. agreed to a $137.5 million fee and a five-year injunction and settlement agreement with the United States Department of Justice and the U.S. Attorney's Office in the Eastern District of Pennsylvania. This landmark litigation will impose extensive forthcoming requirements on AdvancePCS which are designed to promote transparency and restrictions on drug interchange programs.

The settlement requires AdvancePCS to:

- Disclose in new or amended contracts with Client Plans, descriptions of the products and services provided and amounts paid;
- Use the same national data source for pricing to Client Plans and reimbursement to the dispensing pharmacy;
- Provide Client Plans access to information reasonably necessary to audit contract compliance;
- Disclose to each client with an existing or proposed contract that it receives Manufacturer Payments that may or may not be passes through to the Client Plans;
- Disclose to each client with an existing or proposed contract that it will provide quarterly and annual reports detailing the net revenue from sales of prescription drugs to clients and manufacturer payments for the reporting period as a percentage of the net revenue within a range of three percentage points;
- Ensure that contracts with pharmaceutical manufacturers describe all discounts, rebates, administrative fees, fees for service, data utilization fees or any other payments paid to or received by either party;
- And reimburse plan participants for costs related to drug switches up to $200;

AdvancePCS has also entered into a standard five-year Corporate Integrity Agreement, which includes the requirements of training, policies, a confidential disclosure program, and certain hiring restrictions. Additionally, AdvancePCS is required to develop procedures to ensure that any payments between them and pharmaceutical manufacturers, clients and others do not violate the Anti-Kickback Statute of Stark Law. AdvancePCS must hire an Independent Review Organization to evaluate the adequacy of these procedures.

II. Other Federal District Court Lawsuits

North Jackson Pharmacy, Inc., et al. v. Medco Health Solutions, Inc., et al.- On October 1, 2003, three related lawsuits were filed in the U.S. District Court for the Northern District of Alabama against Advance PCS and Caremark (Case No. CV-03-2695), Express Scripts (Case No. CV-03-2696-NE, and designated as the lead case), and Medco Health Solutions, Inc. (Case No. CV-03-2697). In these actions, *North Jackson Pharmacy* plaintiffs allege that the PBM defendants engaged in price fixing and other unlawful concerted actions to restrain trade in the dispensing and sale of prescription drugs. The complaint alleges that the defendants actions have harmed participants in programs or plans who have purchased their medications from retail pharmacies. *North Jackson Pharmacy* plaintiffs allege that the defendants engaged in various forms of anticompetitive conduct citing violations of the Sherman Act, including: (1) setting pharmacy reimbursement rates at unreasonably low levels; (2) imposing vertical maximum prices restrictions for how much pharmacies can charge PBMs and how much the PBMs may reimburse the retail pharmacies; and (3) operating illegal tying arrangements through horizontal price-fixing.

On October 13, 2004, the court in the Express Scripts (Case No. CV-03-2696-NE, and designated as the lead case), and Medco Health Solutions, Inc (Case No. CV-03-2697) cases denied defendants' motion to dismiss the second amended complaint. (*see* Opinion Regarding Motion to Dismiss Second Amended Complaint, October 13, 2004). The defendants alleged that the *North Jackson Pharmacy* plaintiffs' allegations failed to convincingly explain how consumers or the marketplace were injured as a result of the defendants' alleged anticompetitive behavior. The court, however, ruled that the complaint provided the PBMs and drug manufacturers with fair notice as to the nature and basis of the claims set forth against them. On November 1, 2004, defendants filed their answers to the second amended complaint. These cases were then transferred to the US Dist. Court for the Eastern District of Pennsylvania on September 15, 2006 with Judge John P. Fullam presiding (2:06CV04114 and 2:06CV04115 respectively).

On August 3, 2004, the *North Jackson Pharmacy, Inc, v. Caremark Rx, Inc.* case (Case No. CV-03-2695) was transferred to the U.S. District Court for the Northern District of Illinois. (Case No. 04-c-5674). In November 2004, citing to the Alabama court's October 13 denial of defendants' motion to dismiss in the related actions, the Illinois court also denied Caremark's motion to dismiss (*see* Memorandum Order, November 2, 2004). Accordingly, that court proceeded and on November 19, 2004 heard arguments on class certification. On March 22, 2006, this case was transferred to another Judge within the same court, Judge Samuel Der-Yeghiayan who consequently dismissed the case without prejudice on March 24, 2006 allowing plaintiff to file a motion to reopen the case within 10 days. Case was reopened on April 12, 2006, but was transferred to the US Dist. Court for the Eastern District of Pennsylvania on September 16, 2006 with Judge John P. Fullam presiding (2:06CV04305).

Pharmaceutical Care Management Association v. the District of Columbia, et al. - On June 29, 2004, the Pharmaceutical Care Management Association (PCMA) filed suit in the U.S. District Court for the District of Columbia (Civil No. 04-cv-01082) seeking an injunction to block enforcement of Title II of the Access Rx Act of 2004. Title II of this Act requires transparent business practices among PBMs and states that PBMs owe a fiduciary duty to a covered entity. The Act requires that PBMs notify a covered entity of any conflict of interests, and that PBMs pass payments or benefits on in full to a covered entity where the PBM has received from any drug manufacturer or labeler any payment or benefit of any kind in connection with the utilization of prescription drugs by covered individuals, including payments or benefits based on volume of sales or market share. The Act also requires that PBMs, upon request by a covered entity, must provide information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs (including all rebates, discounts, and other similar payments). It requires that PBMs disclose to covered entities all financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug manufacturer or labeler. Finally, the Act sets forth certain provision which must be applied to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual.

In its lawsuit, PCMA argues that Title II is pre-empted by ERISA and the Federal Employees Health Benefits Act in determining who is (and who is not) a fiduciary of an ERISA-covered plan and FEHBA's comprehensive regulation of federal employee plans. Second, PCMA asserts that the law's disclosure requirements effect an unconstitutional taking of PBMs' property by destroying the value of trade secrets. And, finally, in seeking an injunction, PCMA argues that Title II violates the Commerce Clause of the Constitution. AARP has filed a motion for leave to file an *amici curiae* brief in support of defendants (*see* Motion for Leave to File a Brief *Amici Curiae*, July 22, 2004).

On December 21, 2004, the Court granted PCMA's motion for interim injunctive relief enjoining the District of Columbia from enforcing Title II of the Act. The court concluded that the plaintiff had demonstrated substantial likelihood that at least part of Title II may be unconstitutional; that aspects of Title II would represent an illegal takings of private property; and, that Title II could have the unintended effect of actually driving the PBM business and its attendant benefits out of the District of Columbia. That decision is being reconsidered in light of the decision in *PCMA v. Rowe*.

Pharmaceutical Care Management Association v. Rowe This lawsuit filed on September 3, 2003, in the U.S. District Court for the District of Maine (Civ. No. 03-153-B-W), seeking declaratory and injunctive relief from LD 554 with regard to the fiduciary obligations and disclosure requirements set forth in this Maine law enacted in 2003. LD 554 imposes extensive duties of disclosure from the PBM to the client, including the duty to disclose: (1) any "conflict of interest"; (2) "all financial and utilization information requested by the covered entity relating to the provision of benefits"; and, (3) "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and any prescription drug manufacturer or labeler, including, without limitation,

formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees. . . ." While the Act allows a PBM to substitute a lower-priced generic drug for a therapeutically equivalent higher-priced prescriptive drug, it prohibits the PBM from substituting a higher-priced drug for a lower-priced drug unless the substitution is made "for medical reasons that benefit the covered individual" and the "covered entity". The Act also imposes disclosure and approval obligations on the PBM before any drug interchange. It also requires that benefits of special drug pricing deals negotiated by a PBM be transferred to consumers rather than being collected as profit by a PBM. The Act contains a limited confidentiality provision, as well: if a covered entity requests financial and utilization information, the PBM may designate the information as confidential and the covered entity is required not to disclose the information except as required by law.

In its lawsuit, PCMA alleged violation of the Commerce Clause by having extraterritorial effect and discriminating against out-of-state companies in favor of in-state companies; and, "taking" of property for which just compensation is due under the Fifth and Fourteenth Amendments of the United States Constitution. PCMA also argued that ERISA preempts this state law. On March 9, 2004, a decision by the judge temporarily blocked the implementation by issuing a preliminary injunction of LD 554. On April 13, an order was issued by U.S. District Judge D. Brock Hornby that rejected PCMA's challenge to the Maine statute.

Pharmaceutical Care Management Association appealed and the case went to the U.S. Court of Appeals for the First Circuit (Case No. 05-1606). Trial began on April 26, 2005.

On November 8, 2005 the federal district court granted summary judgment in favor of Maine on all claims. Furthermore, the First Circuit Court of Appeals upheld this decision unanimously blocking the attempted PBM strike down of a Maine statute requiring them to disclose information regarding rebates from pharmaceutical manufacturers.

In re Pharmaceutical Industry Wholesale Price Litigation – Originally filed in multiple jurisdictions in 2001, this consolidated class action case was initiated on September 6, 2002 in the U.S. District Court for the District of Massachusetts. (MDL No. 1456; Civil Action No. 01-cv-12257-PBS). The consolidated complaint alleges that the forty-two (42) defendant drug manufactures violated RICO and eleven (11) unfair and deceptive trade practices acts, including the Clayton Act, the Sherman Act, antitrust status of 22 states, state consumer protection statutes in 11 states, and civil conspiracy law. Specifically, defendants allegedly engaged in fraudulent conduct by artificially inflating the average wholesale prices ("AWP") for at least 321 identified drugs causing plaintiffs to substantially overpay for those drugs. Plaintiffs allege that defendants used this AWP fraud to increase market share for their drugs covered by MediCare Part B, and to maintain the high price of their brand name drugs outside of MediCare Part B. Plaintiffs claim that they are damaged by this fraudulent conduct since they are frequently required to make either full payment or copayments for a covered drug or a brand name drug and such payments are based on inflated AWPs.

In February 2004, the court issued a ruling that the plaintiffs had set forth sufficient facts to state claims concerning: (1) the alleged RICO enterprises between the drug manufacturer and four PBMs with the common objective of promoting fraudulent AWPs; (2) the alleged price-fixing conspiracy of one prescription card program in violation of antitrust laws; and, (3) RICO claims involving multi-source drugs. The court accepted class plaintiffs arguments which proposed that the drug companies had manipulated the prices of multi-source and generic drugs, claims which had previous been dismissed by the court without prejudice. Importantly, the order let stand the allegation of an ongoing conspiracy between the drug manufacturers and PBMs, who allegedly profit from the spread between the discounted price they pay and the AWP for which they are reimbursed by patients and other payers. (*See* Memorandum and Order, February 24, 2004).

Peabody Energy Corp. v. Medco Health Solutions, Inc., et al. - Peabody filed this lawsuit suit in Missouri against Medco Health Solutions on April 2, 2003 (Case No. 03-cv-417-ERW) alleging violations of ERISA; this case was filed under seal. In December 2003, the case was transferred to the multidistrict litigation case in the Southern District of New York, in order to consolidate pretrial proceedings (see Order of MDL Transfer, December 10, 2003) (see below, In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation, which was initiated on March 12, 2003).

Gruer v. Merck-Medco Managed Care, L.L.C.;Green v. Merck-Medco Managed Care, L.L.C.;,Bellow v. Merck-Medco Managed Care, L.L.C.;Janazzo v. Merck-Medco Managed Care, L.L.C.;* and,*O'Hare v. Merck-Medco Managed Care, L.L.C.*(also referred to as *In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation, MDL Case No. 1508) - This action was initially commenced on December 17, 1997, with the filing of the *Gruer* complaint. The *Gruer* case was soon consolidated by the court with five other cases each of which asserted substantially similar claims to those presented in the *Gruer* complaint. The complaints that comprise the action, sought class action status on behalf of all individuals who were fiduciaries, beneficiaries, or participants or in employee welfare benefit plans that provided prescription benefit coverage. Class status applied to individuals who: (1) had contracts with Medco or any subsidiaries of Merck; (2) received prescription benefit services from Medco during the Class Period; and (3) used on an "open" formulary basis Medco's Preferred Prescriptions Formulary or Medco's Rx Selections Formulary. The action asserts claims against Medco and Merck for breaches of fiduciary duty and other violations under ERISA.

The Court preliminarily approved settlement of the cases on July 31, 2003. On May 25, 2004 the court approved a $42.5 million settlement proposal offered by Medco Health Solutions to the employee welfare benefit plans. The settlement applied to those who directly or indirectly (through third party administrators, HMOs, insurance companies, Blue Cross Blue Shield entities or other intermediaries) held contracts with Medco between December 17, 1994 and May 25, 2004. This settlement was reached to conclude lawsuits which alleged that Medco violated its fiduciary duty by promoting more expensive drugs made by Merck and other manufacturers over less costly alternatives.

The court did not rule on the merits of either the plaintiffs' claims or the defendants' defenses. This settlement was recently reversed by the Second Circuit.

Healthfirst, et al v. Merck-Medco, et al. - In this lawsuit filed on July 11, 2003, Healthfirst, a managed care prescription drug benefit program consisting of retail and mail pharmacy services, claimed that Medco breached its contract obligations by: (1) concealing the full amounts of manufacturer rebates and discounts it received with regard to Healthfirst's plans, and failing to pass through to Healthfirst any payments to which it was due; (2) demanding additional dispensing fee payments, which were outside the scope of the contract; (3) demanding monies for alleged savings derived from the Managed Rx Coverage Program and the Managed Prior Authorization Programs, while concealing both the amounts and sources of these alleged savings. Discovery in this case continues.

Brady Enterprises, Inc., et al. v. Medco Health Care Solutions, Inc., et al. **and** ***Bellvue Drug Co., et al. v. Advance PCS - In re: Pharmacy Benefit Managers Antitrust Litigation*** - These companion lawsuits were filed on August 15, 2003 in the U.S. District Court for the Eastern District of Pennsylvania by individual pharmacies, as well as the Pharmacy Freedom Fund and the National Community Pharmacists Association. (Civ Nos. 03-4730 and 03-4731, respectively). The lawsuits allege that each of the defendant PBMs have violated Section I of the Sherman Act by engaging in anticompetitive conduct which substantially affects interstate commerce. These alleged violations include: negotiating and fixing reimbursement levels and rates, restricting the level of service offered to customers, and arbitrarily limiting the ability of retail pharmacies to compete on a level playing field with the PBMs' mail order pharmacy. The lawsuits seek class action status and allege that, acting as the common agent for plan sponsors, the two PBMs limited competition by: (1) setting reimbursement rates for pharmacies far below the rates that would apply in a competitive market; (2) fixing and artificially depressing the prices to be paid to pharmacies for generic drugs; (3) prohibiting retail pharmacies from providing more than a 30-day supply of drugs while the PBMs' own mail order pharmacies routinely provide a 90-day supply; (4) requiring retail pharmacies to charge an effectively higher co-pay than the co-pay that the PBMs' own mail order pharmacies charge; and, (5) imposing one-sided contracts and added costs and inefficiencies on retail pharmacies.

The lawsuit against Advance PCS asserts two antitrust violations: (1) horizontal price-fixing conspiracy/agreement among buyers of prescription drugs; and, (2) abusive business conduct by the defendant to harm retail pharmacies. In March 2004, the court denied Advance PCS' motion to dismiss (*see* Memorandum and Order, March 3, 2004). In June 2004, the defendant filed a motion seeking to compel arbitration of the claims and dismissing the court action. (*see* Motion to Compel Arbitration, June 21, 2004). In August 2004, this motion was granted and the lawsuit was stayed pending the outcome of arbitration (*see* Memorandum and Order, August 23, 2004). Plaintiffs filed a motion for reconsideration, or in the alternative, for certification for interlocutory appeal (*see* Motion for Reconsideration, September 7, 2004), which was denied on June 17, 2005. Judge Eduardo C. Robreno ordered on Sept. 20, 2005 this case be placed in the suspense.

On August 25, 2006 this case was transferred and renamed *In re: Pharmacy Benefit Managers Antitrust Litigation* (06-md-01782) and assigned to Judge John P. Fullam for coordinated or consolidated pretrial proceedings.

The lawsuit against Medco asserts the same antitrust violations as in the Advance PCS case and names Merck as a co-defendant on the grounds that Medco is merely the "alter ego" for Merck in promoting its brand name drugs. On November 17, 2003, defendants filed a motion to dismiss for failure to state a claim. In August 2004, the judge issued an order denying this motion to dismiss (citing to and supporting the judge's March 2004 ruling in the Advance PCS case); concluding that the Pharmacy Freedom Fund and the National Community Pharmacists Association do have standing to seek declaratory and injunctive relief; and, that plaintiffs' assertions of Merck's control over Medco were sufficient to withstand dismissal. (*See* Memorandum and Order, August 2, 2004). As such, a scheduling order was issued in September 2004 setting forth the discovery schedule extending well into 2005 (*see* Scheduling Order, September 30, 2004). On August 25, 2006 this case was transferred and renamed *In re: Pharmacy Benefit Managers Antitrust Litigation* (06-md-01782) and assigned to Judge John P. Fullam for coordinated or consolidated pretrial proceedings.

On December 18, 2006 Judge Fullam vacated the August 2004 order granting defendant's motion to compel arbitration as well as a stay of the proceedings (*See* Memorandum and Order, Dec. 18, 2004). Caremark F/K/A Advance PCS appealed this decision to the 3rd Circuit (07-1151) on January 24, 2007. Both cases, the consolidated lower court case and the court of appeals case are pending.

American Medical Security Holdings Inc. v. Medco Health Solutions, Inc. – This lawsuit was filed on May 14, 2003 in the U.S. District Court for the Eastern District of Wisconsin (Case No. 03-cv-431-WCG) by American Medical Security Holdings Inc., a former customer of Medco based in Green Bay. The suit alleged breach of contract involving discounted pricing and prescription dispensing fees. This case settled on March 24, 2004 with Medco agreeing to pay American Medical Security Holdings $5.85 million.

III. State Court Lawsuits

California

***In re Pharmacy Benefits Managers Cases* (Case No.** JCCP4307) – On March 17, 2003, the Prescription Access Litigation Project (PAL) and the American Federation of State, County, and Municipal Employees (AFSCME), AFL-CIO, filed suit against the nation's four largest PBMs for inflating prescription drug prices: Advance PCS, Express Scripts, Medco Health Solutions, and Caremark Rx.

The lawsuit, filed in California, charges that through a pattern of illegal, secret dealings with drug companies the PBMs force health plans and health care consumers to pay inflated prescription drug prices. The lawsuit also alleges that the four drug benefit

managers have reaped billions of dollars in illegal profits by steering health insurers and health care consumers into reliance on more costly drugs. It also contends that the four PBMs have negotiated rebates from drug manufacturers and discounts from retail pharmacies but haven't passed those savings on to health plans and consumers; instead they've used those savings to illegally increase their own profits.

This case is currently pending in the California Superior Court of Los Angeles County.***Alameda Drug Co., Inc, et al.. v. Medco Health Solutions, Inc., et al.***- On January 20, 2004 this lawsuit was filed in the Superior Court of California (San Francisco) (Case No. CGC-04-428109) seeking class action status for California retail pharmacies and pharmacists. The complaint alleges violation of California's Cartwright Act (Section 16720, *et seq.*, of the California Business & Professions Code) by fixing, raising, stabilizing and maintaining prices of prescription drugs manufactured by Merck and others at supra-competitive levels. The complaint also alleges violations of the California Unfair Competition Law by the defendants' unfair, unlawful and/or fraudulent business acts, omissions misrepresentations, practices and non-disclosures. The complaint relies upon information from the U.S. government's *qui tam* case in the Eastern District of Pennsylvania and alleges that Medco has unfairly increased its market share, increased its market power and restricted price competition at the expense of the plaintiffs and to the detriment of consumers. The complaint alleges that since the expiration of a 1995 consent injunction entered by the U.S. District Court for the Northern District of California, the defendants have failed to maintain an Open Formulary (as defined in the consent injunction). Furthermore, the complaint alleges that Merck has fixed and raised the prices of its drugs and those of other manufacturers' who do business with Medco above competitive levels, while at the same time reducing the amount of reimbursement to the plaintiffs for dispensing these drugs under Medco Health Plans.

Florida

Fowler, Florida ex rel. v. Caremark Rx Inc. – This whistleblower case was filed in January 2003, in Leon County Circuit Court by two pharmacists, Michael and Peppi Fowler who worked at Caremark's mail-order center in Fort Lauderdale. The case was filed under Florida's False Claims Act alleging that Caremark engaged in six fraudulent schemes: (1) failing to provide a credit for returned prescription drugs; (2) changing prescriptions without proper approval; (3) misrepresenting the savings obtained from its recommendations; (4) failing to substitute a generic version of "Prilosec;" (5) failing to credit for prescriptions lost in the mail; and (6) manipulating the mandatory times for filing prescriptions. The state of Florida declined to become involved in the case initially but then sought to intervene. However, on July 27, 2004, the judge ruled that the Florida's Attorney General Office had not provided sufficient legal reasoning to justify its intervention more than a year after it had declined to become involved.

Three amended complaints were filed in this case, but the court ruled in favor of Caremark on the merits. It went to the 7th Circuit on appeal (No. 06-4419). On July 27, 2007 the appeals court affirmed the lower court decision on the merits.

New Jersey

***Group Hospitalization and Medical Services, d/b/a CareFirst Blue Cross Blue Shield v. Merck Medco Managed Care, L.L.P., et al. - No. 03-cv-4144* (N.J. Super. Ct. 2003)** -- In this suit, the plaintiff Group Hospitalization and Medical Services, d/b/a CareFirst Blue Cross Blue Shield ("CareFirst") alleges state law claims for breach of fiduciary duty, breach of contract, negligent misrepresentation and unjust enrichment, and claims arising under District of Columbia and New Jersey state statutes against Merck-Medco Managed Care, L.L.P. ("Medco"). As a common law fiduciary, Medco had a duty to manage CareFirst's prescription drug benefits solely its best interest, and to act with undivided loyalty toward CareFirst. Medco was precluded via its fiduciary status from self-dealing or profiting at CareFirst's expense. Subsequent to the expiration of its Agreements with Medco, CareFirst has alleged that Medco breached those Agreements and its fiduciary duties in at least the following ways:

1. failing to require generic substitution at mail and retail;
2. manipulating pricing at retail and mail so as to regularly and systematically bill claims at rates other than those set forth in its Agreements with CareFirst, in order to profit at CareFirst' s expense;
3. concealing the full amounts of manufacturer rebates and discounts it received with regard to CareFirst's plans, and failing to pass through to CareFirst the full amount of rebates to which it was due;
4. choosing drugs for its Preferred Prescriptions Formulary based on which drugs would garner the most rebate monies for Medco, rather than based on which drugs would be most cost-effective and efficacious for CareFirst;
5. engaging in drug switching to higher priced drugs without medical justification; and
6. failing to meet performance standards defined in its Agreements with CareFirst.

New York

New York Unions v. Express Scripts, Inc., et al. – This lawsuit was filed before the New York State Supreme Court in New York County on December 31, 2003, by the United University Professions ("UUP") and the Organization of New York State Managerial Confidential Employees ("OMCE"). The complaint alleges that Express Scripts engaged in fraudulent practices at the expense of union members. According to the suit, Express Scripts negotiated discounts and rebates with drug manufacturers and then unlawfully withheld them from union members. The suit also holds that Express Scripts distorted the Average Wholesale Price (AWP) of its drugs which artificially inflated drug prices to union members. This case is pending.

People of the State of New York v. Express Scripts, Inc., et al. – This breach of contract lawsuit was filed on August 4, 2004 in New York State Supreme Court in Albany County. The suit was the result of a one-year investigation by Attorney General Spitzer's office in cooperation with the Department of Civil Service and the Office of State Comptroller. The investigation was sparked by audits of Express Scripts conducted by Comptroller in 2002. Plaintiffs are seeking injunctive relief, restitution, damages, indemnification and civil penalties resulting from defendants' breaches of contract. The lawsuit alleges that Express Scripts: (1) enriched itself at the expense of the Empire Plan (New York State's largest employee health plan) and its members by inflating the cost of generic drugs; (2) diverted to itself millions of dollars in manufacturer rebates that belonged to the Empire Plan; (3) engaged in fraud and deception to induce physicians to switch a patient's prescription from one prescribed drug to another for which Express Scripts received money from the second drug's manufacturer; (4) sold and licensed data belonging to the Empire Plan to drug manufacturers, data collection services and others without the permission of the Empire Plan and in violation of the State's contract; and, (5) induced the State to enter into the contract by misrepresenting the discounts the Empire Plan was receiving for drugs purchased at retail pharmacies. The lawsuit also alleges, that in furtherance of its scheme to divert and retain manufacturer rebates that belonged to the Empire Plan, Express Scripts disguised millions of dollars in rebates as "administrative fees," "management fees," "performance fees," "professional services fees," and other names. It further alleges that the drug switches caused by Express Scripts often resulted in higher costs for plans and members.

Ohio

Ohio v. Medco Health Solutions, Inc. - On December 22, 2003 the state of Ohio filed a lawsuit in Hamilton County Common Pleas Court against Medco Health Solutions. The suit held that the State Teachers Retirement System of Ohio was overcharged millions of dollars for prescription drugs. The State Teachers Retirement System sought up to $50 million from Medco, including $36 million in alleged overcharges for the dispensing fees on mail-ordered medications. Other allegations claim that Medco undercounted pills when filling prescriptions and permitted non-pharmacists to dispense and cancel patient prescriptions without the necessary oversight by a licensed pharmacist. The case also

contended that Medco steered doctors, pharmacists, and patients to choose brand-name and higher-cost medications manufactured by Merck rather than selecting generic equivalents. On December 19, 2005 the Plaintiff's verdict found Medco liable for constructive fraud and awarded $7.8 million total, $6.9 million in damages plus $915,000 for the State Teachers Retirement System. It was found that PBMs have a fiduciary responsibility. And numerous settlement agreements involving varying degrees of information disclosure strongly recommend transparency as a reasonable solution to the problem.

West Virginia

West Virginia v. Medco Health Solutions- ; Filed in November of 2002 in Kanawha Circuit Court, the West Virginia Attorney General alleged that Medco withheld prescription drug rebates and other savings from the State's Public Employee Insurance Agency ("PEIA"). A central complaint of the case held that Medco deliberately steered PEIA members to purchase Merck manufactured medications even though they were more expensive than therapeutically equivalent alternatives. Another allegation against Medco charged that Medco failed to pass manufacturer rebates on to the consumer. Concurrent to the suit filed by the State against Medco, Medco filed a suit against the State alleging that the State failed to pay for $2.2 million owed Medco by the State of West Virginia. In December 2003, the circuit court granted Medco's motion to dismiss several of the claims. The judge dismissed allegations of Medco's fraud, conspiracy and tortuous interference, and violations of the Consumer Protection Act. The court has permitted the West Virginia Attorney General to re-allege its claims of fraud if it can offer necessary evidence.

Mr. CONYERS. Thank you so much.

We now have a pharmacist, the executive director of the Mississippi Independent Pharmacies Association, Mr. Robert Dozier—Jackson, Mississippi. And he's become one of the State's leading advocates for independent pharmacists by ushering in legislation through his State, ensuring that pharmacies receive timely reimbursement.

And we'd like to hear from you now, as our final witness. Welcome.

TESTIMONY OF ROBERT DOZIER, EXECUTIVE DIRECTOR, MISSISSIPPI INDEPENDENT PHARMACISTS ASSOCIATION

Mr. DOZIER. Good morning, Chairman Conyers, Ranking Member Keller and Members of the Committee. My name is Robert Dozier, and I am the Executive Director for the Mississippi Independent Pharmacies Association.

The local community pharmacies I represent play a vital role in our health care delivery system, but they are being forced out every day by unfair business practices by the major pharmacy benefit managers and the Medicare Part D plans. This is the very reason why the Mississippi Independent Pharmacies Association was formed and why I am before you today at this hearing.

Independent pharmacists are one of the most trusted professions of this country and are the only health care provider that gives free, no-appointment-necessary, trusted care. These pharmacists pride themselves on being able to serve their patients and communities with the highest service. Most independent pharmacies provide 24-hour emergency care, such as helping a mother with a sick child in the middle of the night. Nearly all independent pharmacies provide delivery services to their patients, despite rising fuel costs in today's markets.

To give you an example about the service independent pharmacies provide to the community, Ms. Jane Paschall from Holly Springs, Mississippi, stated in February of 2006 that she was sick and could not drive to town to pick up her medication, so her local independent pharmacist, Bob Lomenick, delivered her medication free of charge, placed her trash out by the road, and when he arrived he even brought her a milkshake from his local pharmacy.

Ms. Paschall stated later that she would've never received that kind of service from anybody but an independent pharmacist. I might add that Bob Lomenick performed all of these services in the middle of an ice storm that was passing through north Mississippi.

In the aftermath of Hurricane Katrina, we saw what independent pharmacists were really made of, when the majority of health care institutions and facilities had been destroyed by the storm. The independent pharmacists of the Mississippi Gulf Coast who had survived the storm opened their pharmacies the day after the storm, despite having no electricity or modern conveniences, so they could provide for their patients and survivors of the worst natural disaster this Nation has ever witnessed.

Independent pharmacist John McKinney in Moss Point, Mississippi, worked alongside with Dr. Sid Ross, who was working from the pharmacy because his office was destroyed, providing care and medication to the people of the Gulf Coast. Mr. McKinney

made sure that anybody who could produce a medication list or bottles with proper ID received their medication, as long as the medication was not a controlled drug. Mr. McKinney and other community pharmacists on the Gulf Coast provided these survivors with their medication with little or no hope of being reimbursed for the products or their services. They provided these survivors with their medication not for the payment or low reimbursement that all independent pharmacists are seeing today, but they provided the medication because it was the right thing to do.

If it were not for these independent pharmacists, the Gulf Coast and the rest of Mississippi might have seen a major health care disaster. When hospitals, local clinics, chain pharmacies and even Kessler Air Force Base were closed, these local pharmacists rose to the top to provide patient care and service in the time of need of their local communities.

You simply cannot receive that kind of treatment and patient care from a mail-order company. I know this from personal experience, because my father had to evacuate his home in New Orleans due to the storm and he is a mail-order patient. My father is a mail-order patient not by choice, but because his insurance company's PBM has forced him to receive his diabetic medications through the mail. He is one of the many refugees from the storm that had problems receiving their medication, but Bill Mosby, a community pharmacist from Canton, Mississippi, helped my father get his medication when he was unable to get it from the mail-order company.

It only strengthens my belief in the role of our country's independent pharmacists when I think of what could have happened to my father and other patients if they were not able to receive their medications.

I want to point out that the small business of independent pharmacy is unique in that it has little control over the cost paid for a product or control over the price set to sell the product. Yet, when it comes to squeeze savings from the system in this escalating-cost environment, both State and Federal Government turn to pharmacy as if they had control over pricing.

Almost all of the medications that pharmacies dispense are paid by third parties, thanks in part to Medicare Part D benefit that our Government approved a few years ago. But the small, independent pharmacists have no voice in the agreements for reimbursement for the Part D plans, and they are facing smaller margins, low to no profit, and greater debt.

Members of Congress may believe pharmacies can absorb these losses and go on. Many people do not understand business operations or the term "gross margin." It is very simple: If a pharmacist buys a medication for $100 and gets reimbursed $85, then has to wait 6 weeks to be paid, it is just a matter of time before he will have to close his pharmacy. There's no gross margin.

The PBMs have reduced payments in a severe fashion. This is an inequity which needs your attention today. A small business of any type cannot continue to operate if the revenue coming in does not at least match the cost of the product being sold and the overhead needed to serve the consumer.

[The prepared statement of Mr. Dozier follows:]

PREPARED STATEMENT OF ROBERT DOZIER

Good morning Chairman Conyers, Ranking Member Keller, and Members of the Antitrust Taskforce. My name is Robert Dozier and I am the Executive Director for the Mississippi Independent Pharmacies Association. The local community pharmacies I represent play a vital role in our healthcare delivery system—but they are being forced out of business every day by unfair business practices by the major Pharmacy Benefits Managers and Medicare Part D Plans. This is the very reason why the Mississippi Independent Pharmacies Association was formed and why I am before you today at this hearing.

Independent pharmacists are one of the most trusted professions of this country and are the only health care provider that gives free, no appointment necessary, trusted care. These pharmacists pride themselves on being able to serve their patients and communities with the highest service. Most independent pharmacies provide 24 hour emergency care, such as helping a mother with a sick child in the middle of the night. Nearly all independent pharmacies provide delivery services to their patients despite rising fuel cost in today's markets. To give you an example about the service the independent pharmacists provide to the community, Ms. Jane Paschall from Holly Springs, MS, stated that in February 2006 she was sick and could not drive to town to pick up her medication, so her local independent pharmacist Bob Lomenick delivered her medication free of charge, placed her trash out by the road when he arrived and even brought her a milkshake from his local pharmacy. Ms. Paschall stated later that she would have never received that kind of service from anybody but an independent pharmacist. I might add that Bob Lomenick preformed all of these services in the middle of an ice storm that was passing through North Mississippi.

In the aftermath of Hurricane Katrina, we saw what independent pharmacists were really made of when the majority of the healthcare institutions and facilities had been destroyed by the storm. The independent pharmacists of the Mississippi Gulf Coast who had survived the storm opened their pharmacies the day after the storm despite having no electricity or modern conveniences so they could provide for their patients and the survivors of the worst natural disaster this nation has ever witnessed. Independent pharmacist John McKinney of Burnham-McKinney Pharmacy in Moss Point, MS, worked along side with Dr. Sid Ross, who was working from the pharmacy because his office was destroyed, provided care and medication to many of the people on the Gulf Coast. Mr. McKinney made sure that anybody who could produce a medication list or bottles with proper ID received their medication as long as that medication was not a controlled drug. Mr. McKinney and other community pharmacists on the Gulf Coast provided these survivors with their medication with little or no hope of being reimbursed for the products or their services. They provided these survivors with their medication not for the payment or the low reimbursement that all independent pharmacists are seeing today, but they provided the medication because it was the right thing to do.

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I want to point out that the small business of independent pharmacy is unique in that it has little control over the cost paid for a product or control over the price set to sell the product. Yet, when it comes time to squeeze savings from the system in this escalating cost environment, both State and Federal government turn to pharmacy as if they had full control over pricing. Almost all of the medications that pharmacies dispense are paid by third parties—thanks in part to the Medicare Part D benefit that our government approved a few years ago. But the small, independent pharmacies have no voice in the agreements for reimbursement for the Part D plans, and they are facing smaller margins, low to no profits, and greater debt.

Members of Congress may believe pharmacies can absorb these losses and go on. Many people do not understand business operations and or the term "gross margin." It is very simple: if a pharmacist buys a medication for $100 and gets reimbursed $85, then has to wait 6 weeks to be paid, it is just a matter of time before he will have to close his pharmacy. There is no gross margin. The PBMs have reduced payments, in a severe fashion. This is an inequity which needs your attention today. A small business of any type cannot continue to operate if the revenue coming in does not at least match the cost of the product being sold and the overhead needed to serve the consumer.

This is a blow to small business, but devastating to those patients served by these small businesses. Pharmacists across the nation are agonizing over the thought of not being able to serve their patients. And those patients will be distraught over the thought of losing their pharmacies. Members of Congress may not believe access is a problem because they see multiple pharmacies at the same intersection in larger cities. Mississippi is a prime example of rural America, a state that has eleven counties with only one pharmacy and one county that has NO pharmacy at all. These patients understand what it will mean to their health care if that pharmacy disappears—they could easily be 30–40 miles away form the next closest pharmacy.

Independent pharmacies across the state of Mississippi and the United States are a key component of the healthcare delivery system, but they are facing extinction due to the unfair business practices of the major Pharmacy Benefit Managers and Medicare Part D Plans. You can see from my earlier statements how important these small businesses are to our communities. Without the ability to truly negotiate with the PBMs, independent pharmacy will become a thing of the past and our healthcare system in this country will truly be broken beyond the point of fixing. We will never be able to replace the face-to-face patient counseling that community pharmacists provide on a daily basis to all of their patients. There will not be the same care from a mail-order company that we see from an Independent Pharmacist.

Once again, I would like to thank you for your time and I urge that the committee schedule a markup of HR 971 and bring the bill to the floor in order to keep this key component of our health care system in place.

Mr. CONYERS. I thank you, Mr. Dozier.

And I thank all of the witnesses. This has been fascinating.

I've got to go back and find out what happened to Campbell-Conyers over a half-dozen years ago.

Mr. Dozier, you've put a huge burden on my local pharmacist, because I don't get that kind of service. And I'm going to tell everybody, all the local guys in the Detroit area, you know, what may be pretty extraordinary service here.

But, you know, you five have listened to myself, Mr. Keller, Mr. Weiner, Darrell Issa. And each of you listened to four other witnesses.

So I want to just ask you, if we were sitting around whatever it would be in Mississippi, maybe the Cracker Barrel—we're just talking about this now. Forget the fact that you're in a Federal situation where your testimony is reviewed for its accuracy.

But let me ask you, Mr. Dozier, of all the things you heard here this morning from all the rest of us, what is on your mind? What are you thinking about, in terms of the great variety and scope of analysis that's happened here this morning already on this subject?

Mr. DOZIER. Well, my personal feeling is, listening to everybody's testimony and some questions from you all, that there is an urgency that we need to save independent pharmacy in this country of ours.

The gentleman earlier testified that this would run the program up; it would cost $29.6 billion. Personally, myself, I have a hard time believing that. If we do not save independent pharmacy, it will probably cost us $29 billion, because we will see a problem with pharmacy provider access, and therefore you will see hos-

pitalization rates increase because the pharmacist was not there to take care of those patients in those communities.

For example, there have been already 18 to 20 pharmacies, independent pharmacies, to close in the State of Mississippi, from January 1st to the end of August, and that came from the State Board of Pharmacy. There are 11 counties in the State of Mississippi which only have one pharmacy, and that happens to be an independent pharmacy. In the State of Mississippi, if pharmacies continue to close, you will see a major health care disaster because the accessibility to the pharmacy will not be there.

And as we're going out of business, the PBMs and the Medicare Part D plans are making huge profits, obscene profits. And, ladies and gentlemen, Mr. Chairman, we have to remember this: It's about the care of patient.

And the pharmacists are the ones who take care of the patients. The PBMs and the Medicare Part D plans are only concerned about one thing and one thing only: profit, profit and profit.

Mr. CONYERS. Thank you very much.

Dr. Rankin, could I ask you for your impression of the various positions that have been put forward that you hear among the members of the panel and your fellow witnesses?

Mr. RANKIN. Certainly, Chairman.

I think it's certainly true that there is a remarkable tension among the different testimony you've heard. And I think one of the commonalities that you hear or at least one issue that, perhaps, is not disputed is that there is a role, and there is a value to independent pharmacies. The frustration is that there are some pharmacies that are closing, and yet, the economic factors or at least the cause for this points to, according to advocates for the bill, to PBMs.

And so, on the other side of the tension, you have the economic analysis of the PBM industry, which repeatedly shows that it is considered to be a highly competitive industry. When PBMs interact with plan sponsors—those are health insurers and employer groups—there is quite an intricate bidding system that has, over time, become incredibly efficient and has allowed plan sponsors to define the terms and get very good deals, at least in terms of the sharpened-pencil point, in structuring deals with PBMs.

And so the tension, to me, seems really to be one of, if having the services provided by independent pharmacies is one of value and is one that Congress wants to value not necessarily on economic grounds but because it values the services offered by independent pharmacies, there is no role for antitrust exemptions. The PBMs are competitive and have repeatedly demonstrated to be so. And I worry, frankly, about the after-effects of granting exemptions to independent pharmacies.

Mr. CONYERS. Thank you very much.

Mr. Mike James, in sorting out all of these varied opinions and pronouncements, what is the major thing that is impressing you this morning?

Mr. JAMES. Mr. Chairman, as you and I have talked before, as a pharmacist, my main concern in all of this is the health care of the patient. We've always said that the personal relationship of the independent pharmacist is the best cost-containment program

there is, because that pharmacist knows what's going on with the patient. They know what their process is, they know their health care, they know their history.

The problem that I have with what I'm seeing today is that the health care, which is what we are here before the Judiciary Committee today about, is the fact that we're seeing less and less health care being administered to that patient.

I mean, I think about that patient who would walks into my pharmacy who is on Medicare Part D. She has fallen into the donut hole, and she has no way to buy her insulin. It is a true fact. I can give you the lady's name. This is not a hypothetical case.

The process we have here is a program that, when it was first announced, seniors said, "Oh, what a great program this is going to be." They just, unfortunately, didn't know the details of the program. They surely found those out as they found themselves within the program.

The problem we have today is there are so many dollars being taken out of this program that could be retained in the program and eliminate the donut hole. There are ways to do that. You know, I believe there are programs out there, there are plans out there that we can put together to do that very thing.

It's easy for us to sit in this room today and talk about the patients who can't pay for their medication. I can assure you, as you stand in your pharmacy and that patient is in front of you trying to figure out how they are going to get their medication, it is a whole different emotional level of what's going on. And we face that as pharmacists every day, and we work every day to try to help those patients find a way to get their medications.

It is a very difficult situation. It's a situation that exists that shouldn't exist, and that is what we are talking about this morning.

Mr. CONYERS. Thank you very much.

Mr. Wales, what impresses you most about the wide variety of opinions you heard this morning?

Mr. WALES. I would be happy to answer that.

Let me start off by saying that I think we are sympathetic to some of the issues that have been pointed out, in terms of some of the shortcomings with respect to our health care policy in the U.S.

I, personally, grew up in a pretty small community in upstate New York. In fact, I've seen some of the challenges that are faced by communities in terms of not only pharmacy services but doctor services. And so I think—let me start by saying that I think we realize that there are some real challenges there.

I think the problem is that we really don't think a broad, you know, kind of antitrust exemption that would apply across markets and apply in different circumstances is the right answer to some of those problems.

There are certain things we do know. We have seen collective bargaining by health care professionals that has really had a negative impact on American consumers. It has driven the prices up of health care services. We've seen pharmacists who, I think—you know, I really do think we do appreciate them. There are a lot of great pharmacists out there. Unfortunately, there are some bad apples who have been out there, you know, with the goal of increas-

ing compensation, really, untied to quality-of-care issues. And so I think the problem is that we really do believe in the benefits of competition in those markets, and we have seen some of the real downsides to consumers when that competition is taken away.

In essence, I think there are some, really, more narrow quality-of-care issues that are raised by this panel. And I think, you know, hopefully, the challenge is trying to focus on those without a broader antitrust immunity that goes into areas that we think have unintended consequences and will actually harm consumers.

Mr. CONYERS. Thank you.

Attorney Balto, your view?

Mr. BALTO. Thank you, Mr. Chairman.

You know, let me start off with H.R. 1304.

By the way, last night, I got to talk to Congressman Campbell, and he sends you and the Committee his regards. He is having fun running the Haas School of Business.

He wanted me to say, look, the Congress had enacted the Sherman Act. You know, go back to that sword of Damocles. They saw the antitrust laws not as a sword for the PBMs to use, for the big insurance companies, for the big intermediaries to use to bully small producers, but, rather, as a shield to protect those small producers from the anticompetitive activity of those large intermediaries.

That's why you've acted prudently to pass exemptions, for example, the Standards Development Organization Act or other exemptions that have been passed that are mentioned in my testimony, to go and clarify the law and protect small producers.

Let's go back to H.R. 1304. There are people who said H.R. 1304 shouldn't be enacted. They said, "Wait. Let the antitrust laws work. If the problem is that the insurers and PBMs are too big, we will go and stop them from becoming bigger." Well, what's happened in the last 7 years, and with due deference to my good friend Mr. Wales, the FTC and the Justice Department haven't stepped up to the plate. They haven't challenged any PBM mergers. They didn't issue a second request in the CVS-Caremark merger. They only did a quick, brief look at the Caremark-Advance PCS merger.

By the way, based on that, they issued a statement saying the market is competitive. If you take just a quick look at things, I don't think you can really assess whether or not it's competitive. The result is there are three dominant PBMs, and they use "take it or leave it" offers. You know, they just basically impose "take it or leave it" offers.

It's important for you to realize when you consider these issues, when Mr. Rankin mentions economic grounds or Mr. Wales mentions economic grounds, we're not talking about the production of ice cream, we're not talking about the production of tires; we're talking about health care.

It is in the interest of somebody who has monopsony power to underbuy, to undersupply the market. When you have that power, you want to drive production down. And what that means is that, when I, as an individual, want to go and have my prescription filled, Mr. Dozier's out of business. There is no place for me to go. It means that I can only get my service under mail-order, and that's a cumbersome and often bad process.

Now, we've spoken a lot about the profits of the PBM industry, and I don't deny anybody the ability to secure profits, but what do the profits tell you? They tell you the same thing, Mr. Chairman, that they told you when you had the oil companies in here. Those astronomical profits mean those firms have market power. These independent pharmacists, they don't have market power. Rite Aid is acquiring Eckerd's. They don't have market power. But if somebody is making those astronomical profits, that suggests they have market power.

And how do they use that market power? They use it to harm consumers. They engage in a tremendous number of exploitative practices, which my testimony has an appendix of all of the cases that have been brought against the PBMs. They have had to pay, so far, over $300 million in damages.

Let me stop with one final comment about mail-order. And I do not want to get into a debate over here, but I spend 60 percent of my time representing consumer groups—Consumers Union, Families USA and USPIRG—and they do not like mail-order. We don't like mail-order. It may appear to save the employer money. It may be a rich source of profits for PBMs. But ultimately, it leads to worse patient care. Ultimately, it leads to worse health outcomes.

The better system, the preferable system, is empowering the community pharmacists, allowing them to do 90-day scripts, allowing them to provide the high-quality service that consumers need. Otherwise, you will wake up 5 years from now, Mr. Chairman, having to fill a prescription, and you're going to have to pick up a phone and call some pharmacist in Thailand, who works for a PBM, who will be trying to answer your questions about—you know, instead of being able to go to your neighborhood community pharmacist. That's why this legislation is necessary.

Mr. CONYERS. Well, thank you for your measured predictions of what is going to happen in the future.

I now turn to the author of the legislation which has brought us together, the gentleman from New York, Mr. Anthony Weiner.

Mr. WEINER. Thank you, Mr. Chairman.

And I thank the panel. It has been enlightening.

Mr. Rankin, who paid CRA International for this study?

Mr. RANKIN. This study was commissioned by PCMA.

Mr. WEINER. What is PCMA?

Mr. RANKIN. It is the trade organization representing PBMs.

Mr. WEINER. In your estimate of the cost of this $29.6 billion, according to your models, how much of that would be absorbed by a PBM's bottom line?

Mr. RANKIN. The model does not predict an exact number. If you read the report, what it says is $29.6 billion over 5 years. And based upon the recognition of competition in the PBM industry, the expectation is that most of that would be passed through to plan sponsors.

Mr. WEINER. Well, I see cost-simulation scenarios that go into great questions about elasticity, where it would lie, the total incremental gross margin increases for TPP prescriptions. Nowhere could you—no modeling could calculate, given that there is a limit on how much is going to PBMs by the Government—so you should be able to recognize that some of it would be absorbed in different

points along the consumer stream. You can't in any way estimate how much of that would be absorbed by PBMs?

Mr. RANKIN. The estimate that you are looking for really depends on how plan sponsors interact with their PBMs.

Mr. WEINER. I would agree with that.

Could it be that $29.6 billion in your study, since you don't model it to see where that will be distributed—to taxpayers in the form of Medicare payments, to pharmaceutical companies themselves, or to consumers—could it be that PBMs would absorb all of it?

Mr. RANKIN. No.

Mr. WEINER. Tell me why.

Mr. RANKIN. Because PBMs compete vigorously for services provided to plan sponsors.

Mr. WEINER. PBMs, in their creation, were created in order to take the amount of money that Government was allocating for the drugs and to process all of the various people trying to get the drugs, in a way, to save money.

Now, if we create this and there is increased competition and PBMs are going to have to pay out or they're going to have to pay more to pharmacists, why could it not just be, since PBMs can't go to Government and say, "Give us more money," that PBMs will have to absorb it?

Mr. RANKIN. There's nothing to absorb, is the point. When plan sponsors interact with PBMs, they provide very detailed RFPs. These are specific categories of services that need to be provided by the PBMs. They engage, typically, in at least two rounds of bidding, in which PBMs provide full documentation. And during this process, plan sponsors usually retain benefit consultants who serve this role over a number of negotiations and develop a familiarity with both the tools and the methods employed by PBMs——

Mr. WEINER. Let me just interrupt you for a second. You have calculated, under your contract with PBMs to do research, you have calculated a number that is exquisite in its precision, $29.6 billion. A classic tool of consultants, to make it seem like it is a precise estimate. You make it $29.6 billion rather than $30 billion.

Hey, well, that gives it a certain intellectual heft, I guess, but I have asked you whether you modeled to figure out where in the consumer stream that you broadly say that it can go to—consumers or it can be returned to Medicare. And nowhere is there anywhere in the modeling as to what percentage of it that just the PBMs will have to take since they're now facing another organized group, competing together to negotiate for lower prices, just like Rite Aid or Eckerd's or anyone else. Nowhere is it characterized in here how much the PBMs would absorb.

And I think the reason that it's not characterized that way is because there's a chance that it can be $1 of it. I mean, you say none of it. I find that hard to believe. It could be $1 of it.

Theoretically, let us assume for a moment independent pharmacies are able to organize. By your own definition, they are getting $29.6 billion of additional reimbursements for the drugs that they're selling. Well, that cost could, absent any other information to the contrary in your study, be absorbed by PBMs.

Mr. Wales—certainly, go ahead, Mr. Rankin.

Mr. RANKIN. Everything you say is contrary to economic theory, to the statements of the FTC and to the economic research we have done.

Mr. WEINER. Well, we're going to get to the FTC in a moment. Mr. Rankin, you had an opportunity——

Mr. RANKIN. Yes.

Mr. WEINER [continuing]. To model this. For example, if I asked you now—assume for a moment that the Federal Government wanted to model it so that all of it, all of the additional costs, would be absorbed by the PBMs.

I can think not—you know, being a Member of the Energy and Commerce Committee, I would probably take about 25 minutes to how I would write that bill. I would say that the PBMs are going to get X number of dollars for a drug. That is going to be our reimbursement rate to the PBM. You then have to go out and negotiate your prices with your Rite Aids, your Eckerds and these independent pharmacies, and whatever price you get, if it is not $10 like it was yesterday and if it turns out to be $9 because of tougher competition, it is $1 out of your employer's hide.

So I can say 100 percent of it comes from the PBMs, couldn't I? Thank you, Mr. Rankin.

Mr. Wales, let me ask you a question on your testimony. You are correct to point to the AMC, the Antitrust Modernization Act. And you point to, I guess, the salient line, that "Exemptions should be necessary"—this is quoting from your testimony, which is from the Act—"necessary to satisfy a specific societal goal that trumps the benefit of a free market to consumers and the U.S. economy in general."

And that is not only the statement of Congress, but it's intuitive that you want to be able to make sure that a goal is advanced. Obviously, the uncontested goal here—I don't see anyone arguing that having fewer community pharmacists is a societal goal. You want more competition by just about any model. No matter who is paying the bills, you want to have competition, you want to have employers and people to have a choice. Your hometown does not benefit by having less competition. It benefits by having more. So it's intuitive that what we're trying to do here is to have more competition, which is the societal goal we're trying to pursue.

The thing that the FTC doesn't realize—and, frankly, it weaves in and out of this fact in its various actions—this is not a free market, is it? I mean, for 90 percent of seniors, they do not have the opportunity to go out and say, for example, "I do not want to get Lipitor. I don't like that—I don't like that drug. My blood pressure is—I'm going to go to something else. I'm going to go out, and instead of getting Lipitor, I am going to go out and shop for five or six or seven other drugs. I'm going to go compare notes, and I'm going to decide for myself."

This is not a classic free market because consumers don't have the expertise, the experience or the choices. Elsewhere in this Committee, we have decided that a pharmaceutical company is going to have an uncontested right to sell that drug and only that drug for a certain period of time. So this is not a free market. We're not going in and deciding which car you're going to buy. We're going in and taking a marketplace that is hyperregulated and

hypercontrolled—and extraordinary powers are vested with the person who controls that drug, whether it controls it at the manufacturer or it controls it at the PBM. We consumers aren't going in and taking a free market and making it an unfree market. We're taking a very, very hyperregulated market and trying to broaden choice for people.

So you have to, in your analysis, look at the idea that you're not looking at a classic free market, and you're certainly not looking at a market as it relates to Medicare Part D. With Medicare Part D, neither the PBMs nor anyone else can go and say to the Government, "We are going to say whatever we want for this price." They agree that if you're going to be in the program, that you're going to have to pay for it.

And I would just point out one other thing. In your testimony, you expressed concern that if my legislation is passed that it takes away the incentive for greater service. Well, I would say to you, my friend, even with the advantage of being able to join together, the only way a neighborhood pharmacist can compete against the Rite Aids is based on service. And I think the record will show today—and you may even want to stipulate to this—that neighborhood pharmacies today survive based on the service of Mr. Dozier. You know, that's the only edge that they have, is they've got to hustle and hustle and hustle. But you can hustle all you want; if you're paying $50 for a drug and the Eckerd down the street is paying $25 for a drug, you aren't reaching that place.

And so, sometimes the antitrust laws are used, or the ability for people to negotiate as a group is a way to do so in a minimally invasive way, rather than going and manipulating the economy. It's a minimally invasive way to say, "Let's figure out a way to try to let these different sides compete."

I see no scenario where allowing this to happen reduces the numbers of players in the marketplace. I just can't figure that out. There's no way a handful of guys in Mississippi are going to drive Wal-Mart out of business. I don't see any real way that a bunch of guys in New York are going to drive Rite Aid out of business.

So, if you game this out, you are going to have a furtherance of the societal goal, more community pharmacists surviving, a furtherance of the societal goal of having more competition based on service—because nothing is going to make Rite Aid improve their service if they're not going to have the neighborhood community pharmacist to compete with—you'd have more competition in this controlled marketplace, so you don't have this pure free-market thing; you have more people that are going to be competing.

And let me just say, finally—because I'm giving you a lot, and I do want you to respond because you're not on any PBM's payroll, so I am interested in your viewpoint as an economic theorist in this case. In no way is it clear who it's going to drive up the cost to. In my exchange with Mr. Rankin, he says, absolutely, it's going to drive it up to everyone but to my bosses. You know, you might have a different view. Tell me.

If I wanted to craft this and you said it should be limited and we should try to figure out a way to craft it—if I wanted to try to craft this in a way that the PBMs had to absorb the cost, how would you recommend I do it?

Mr. WALES. Let me figure where to start.

Mr. WEINER. Go ahead. I have asked a lot of questions here. Take your time.

Mr. WALES. I'll do my best, and I'm sure there will be ones that I miss that you'll hopefully bring me back to.

Just to kind of start at the fundamental concept, I think that, certainly, no one is going to argue that these markets are operating in a perfectly competitive manner. I think there are very few markets in the U.S. that do that.

I think there is also no question that there are some legitimate concerns, in terms of some of the issues that some of the independent pharmacies are facing in the market. Certainly, all things being equal, more competition is better, and certainly, more competition from independents is better.

I think this bill does something very different, in the sense that it takes what we think is very important, in terms of the competition that is existing—and it may not be perfect, but there is no doubt, I think, that there is competition going on between the independents, between the chains—CVS and Wal-Mart and Walgreen's are all competing—and that consumers benefit from that competition.

I think the issue we have with the bill is that it goes and takes these issues, which, I think, are more narrow issues, and it applies it across the board in situations where, you know, there may not be inequities in bargaining power. Certainly, there are examples where there are inequities.

I think the problem is that this bill applies across the board in areas where doctors and pharmacists may have more leverage, and there may be communities right now where pharmacists really do have a lot of bargaining power against the payers and the PBMs, because they are the only game in town. Certainly, that is a possibility. You know, maybe that is a minority of the markets, but certainly that is a complication. I think it is a concern that this bill does not take into consideration and, across the board, removes competition, which we think is vitally important in terms of protecting consumer interests and advancing the things——

Mr. WEINER. If I can stop you, explain to me that part. Where would it remove competition? Tell me how. Can you just kind of game it out for me?

Let's assume you have a community that has one community pharmacist and no Eckerd's anywhere, and that guy forms into a consortium. You're saying there, in that case, if it doesn't end competition, you're still going to have—I mean, I understand there is still competition that exists——

Mr. WALES. Maybe let me go through, and jump in, I guess, if I'm not hitting the point.

I think the way you would look at it is that, when you remove the protections of the antitrust laws, that allows people to price, that allows them to collectively bargain against PBMs and against the payers. I think what we find is that, ultimately—and maybe that is the goal of the legislation, is it raises the reimbursement rates for pharmacists.

What happens is—and this gets into, kind of, what happens after that point—what then happens is that, since this is such a large

input into the PBMs' product that they offer to their customers and then that the payers offer to employers—and I think we kind of agree with the idea that basic economics suggests—and this came up in the 1998 and 1999 test by Chairman Pitofsky—inevitably, you typically do see an increase in the downstream product, and so people are going to pay more for their medicines and for their drugs here. I think that's the fundamental issue that we see here.

Beyond that, I mean, it's not like we're talking about a theoretical exercise here. We have specific enforcement actions we've taken where the exact same scenario that this bill is going to create has happened, where people have violated the law and have gotten together and have colluded in ways and have price-fixed and have boycotted PBMs and payers. That has had a really negative impact, increasing reimbursements by 22 percent and up to 60 percent.

Mr. WEINER. Right. Maybe this will help us perfect the bill. If the bill said, we will suspend antitrust only for the purposes of forming into associations for the purpose of negotiating with PBMs, that that is the sole purpose, would you be satisfied that it would make it impossible to—that you could not price-fix and that you'd still have to get the PBM to agree? You're still a tiny—and I'm sure you know this from the testimony—you're still a tiny percentage of the overall marketplace, compared to the bigger chain stores.

If it were limited just for those purposes, just for the purposes of negotiating deals on pharmaceutical drugs, would that help allay some of your concerns?

Mr. WALES. I don't think it would. The problem is—and I think for the bill, really, to have an impact—I mean, I think that this is really not open to debate, that the plan of the bill is to allow pharmacists to get larger reimbursements. So, if you're getting together and collectively negotiating, you have to have some market power to do that.

You know, Mr. Balto had suggested that there are a lot of instances where independent pharmacists don't have that market power. But if that's the case, then what does this bill do for you? If you can't negotiate and have some leverage with the PBMs, they can go to somebody else, right?

Mr. WEINER. Mr. Wales, you've asked an excellent question. We sometimes have the tendency here, when we debate bills, to wildly overstate and wildly understate the effect of the bill. You know, it could well be that the influence might be more in some places and less in some places. It might be nothing. PBMs are so extraordinarily powerful in this, they might take a group in Mississippi and say, "Hey, guys, we're not going to talk to you. You are now coming to us in association. We are refusing to deal with you. Goodbye." Oxford Insurance, in my district in New York, said to whole hospitals, "You don't like it? Tough. Take a hike."

So it could well be that the PBMs will continue to act in the way that PBMs have acted. And I would refer you to the testimony of Mr. Balto's and to a list as long as my arm of lawsuits brought by consumers against PBMs and by States like my own against PBMs. So it could well be that this might not have a great impact.

You see, this is the problem that I have. We can't say that this is going to have this seismic shift when we know intuitively these

are still tiny players. Just to give them one additional arrow in their quiver, this notion that they're going to transcend from being David into Goliath overnight because of this bill, I think, is overstating the case.

Mr. Balto, do you want to respond since Mr. Wales mentioned your testimony?

Mr. BALTO. Yes. You know, we're ready to—all three of us are ready to give you an economic seminar, but let me explain. Pharmacies are being reimbursed at a suboptimal level. What they're trying to do is get it up to what it should be. What we're all saying is they—well, what all of us are saying is there is no chance these guys can have market power. They might get power enough to get it up to something like the level where it should be, but they're not going to be able to charge super-competitive prices.

Again, the FTC's decision not to protect the poor, weak PBMs of New York against Rite Aid's 40-percent-plus market share in several metropolitan markets in New York City shows you that getting independent pharmacies together is not going to harm the PBMs. Ultimately, consumers aren't going to be harmed.

You know, what we're talking about is a legal rule that you have decided doesn't work in certain circumstances, and you've enacted exemptions that prevent PBMs from going and doing everything that a chain pharmacy does. That's all. And if the chain pharmacies do it, nobody cares. But if the independent pharmacists try to do it, they're saying that a sword of Damocles should befall them.

Mr. WEINER. Let me pivot off of that, because I was thinking the same thing when I was listening to Mr. Rankin's testimony and Mr. Wales' as well.

By the logical extension of your argument, taxpayers, PBMs, the Government and consumers would benefit a great deal if Rite Aid had to negotiate as an individual store, right, that they could not join together?

Mr. Rankin, do you want to take a stab at that?

Mr. RANKIN. I am sorry. The question?

Mr. WEINER. By the logical extension, if this would have such pernicious effects by allowing a small group to band together, it seems to me that the inverse is true, that if we said to Rite Aid tomorrow, "Rite Aid on Avenue U," in my district, "and Rite Aid on Kings Highway, you can't band together as one company and negotiate; you've got to do it as individuals," that would reduce the cost to consumers, wouldn't it?

Mr. RANKIN. I guess I disagree with the premise of your question. And I think one thing that we're losing track of here is the fact that there are access requirements that provide protection right now, and it is those same access requirements that give market share when there is not necessarily 40 or 50 percent.

All you need, frankly, is a handful of independent pharmacies that happen to be, say, the only pharmacy within 15 miles of a rural residence. The inclusion of that pharmacy is absolutely necessary to comply with Federal access guidelines.

Mr. WEINER. Right, I understand.

If you can, just return to my question. You've made the argument that allowing this small group of hardy souls to band to-

gether is going to increase costs to consumers, increase costs to taxpayers, increase costs, period.

Isn't the inverse true, that, if we were to say tomorrow, "Rite Aid," which has hundreds of stores, "you can't negotiate your 600 stores together; you've got to go to the PBMs as individual stores," which is the situation that independents are in now, that that would, by definition, or by your rationale, reduce costs to consumers? Because they wouldn't have the bargaining power and the heft to join together, would they not?

Mr. RANKIN. I don't think that's true.

Mr. WEINER. Oh, okay.

Mr. RANKIN. I think there's at least one aggregation issue that you're overlooking, which is the simple fact that, when PBMs or health plans approach pharmacies to construct a network, pharmacies can say, "No." When you secure Rite Aid, you secure a certain number of pharmacies.

Mr. WEINER. Well, that's preposterous.

Mr. Dozier, explain to him why that's preposterous.

Mr. DOZIER. When a PBM approaches a pharmacy, it's a "take it or leave it" contract, plain and simple.

If I were going to enter into a business deal with you, Mr. Weiner, there'd be some type of negotiating. When a PBM comes to a pharmacy, there's no type of negotiating, none whatsoever. The PBM says, "Here is the contract. This is the reimbursement. These are the terms. You either accept it or you can't be a provider in this network." And if that pharmacist doesn't accept that contract, they're not allowed to serve their patient that they might have been serving for the past 20 or 30 years. That patient is going to have to go down the street to another pharmacy that they don't want to.

Mr. WEINER. Mr. Dozier, thank you.

Mr. Balto, would you explain—because I'm not sure my question put it right. The argument by Mr. Rankin and by Mr. Wales is, if you allow these independent pharmacies of a relatively tiny number to band together, it would raise prices. I asked Mr. Rankin, does that not mean if you take the inverse, that if we had Rite Aid disband and they could only negotiate as individual Rite Aids, it would reduce prices as well, would it not? I mean, by the logical extension, I'm not,you know——

Mr. BALTO. Sure. You know, in the idyllic world of economic theory, it might appear to be good to create unlimited monopsony power. That would be great, you know, if we had agricultural processors with monopsony power. That would mean that we'd have, probably, relatively few farmers, and we would go extraordinarily hungry, because the goal of a monopsonist is to drive output down and to buy as little as possible. And we're not talking about corn here; we're talking about health care.

But let me—you know, the PBMs—by the way, I should say, for full disclosure, I do, actually, do work for pharmaceutical benefit managers. I appreciate both sides of the story here.

The PBMs are suggesting that they're competing on behalf of the plan sponsors. If they were competing on behalf of the plan sponsors, in that index of consumer protection and fraud cases that I have appended to my testimony, you would not see so many cases

brought by plan sponsors against the PBMs. Why? Because the PBMs refuse to disclose information to the plan sponsors so that they can really assure a competitive market, so that, when they undercharge the community pharmacist, they know the value of that deal and they get the best price possible.

I want to be sure that I have a chance to respond to the PCMA estimates. Could I have 2 minutes for that?

I really look forward to going and providing a critique of the PCMA estimates, but, you know, these estimates are only as good as the assumptions they make. And the assumptions they make are terribly flawed.

They suggest that, basically, Mr. James is going to turn the tables on the PBMs, he is going to gag and chain them at the negotiating table. He's going to say, "You know that cash price I get? You have to give me that cash price." We're not talking about 10 or 15 percent. We're talking about something really substantially higher. They use this estimate from North Dakota. Well, the bid that was submitted by the North Dakota group was rejected, and they got far less than that.

Finally, you know, the question, to me, about the additional costs I think are answered by the Rite Aid nonenforcement action by the FTC. If there is a real threat of market power here by your 20 independent pharmacies in Florida getting together, I guarantee you the FTC would never have let Rite Aid acquire Eckerd's.

Mr. CONYERS. Thank you very much.

I am going to ask Mr. Weiner to allow the gentlelady from California, Maxine Waters, a distinguished Member of the Judiciary Committee and who is under some time pressures—we would like to yield to her for any comments or opening statement that she would like to make at this time.

Ms. WATERS. Thank you very much, Mr. Chairman, for your generosity.

I do have to get back to my office, but I wanted to stop by, number one, because I am on the Antitrust Task Force, appointed by you, and I do want to pay attention to these issues. And, of course, I am extremely interested in the subject that is before us today. This Task Force on Antitrust and Competition Policy hearing that you're holding interests me simply because, as a consumer that is involved with having to purchase prescriptions, I had no idea that there was an intermediary that managed all of this. I thought, when I went to my pharmacist, that I was purchasing my medicine from someone who bought it from the manufacturer and that there was a cost, certainly, involved that was negotiated with the manufacturer. I just had no idea that it was all this involved.

Let me just say, Mr. Weiner, that I don't know whether or not your prescription for making it fair to the local pharmacists is the right one, but I'm interested in hearing if, in fact, an exemption, antitrust exemption, would allow them to be able to negotiate with the intermediary—what is it, the PBMs?—that I'm interested in that, because I don't like the idea of moving toward more mail-order prescriptions. I like the idea that I can talk with the pharmacist and ask him more questions about how I should use the medicine and what my experience has been. And I even like the idea of simply having to check off—that they offer to talk to me if

I want to talk, because I am just an old-fashioned person who likes the local pharmacist, the local bank, the local everything. I'm sick and tired of being thrown into these systems where I have less and less control.

So we've got to have a remedy. I don't know whether this is it or not, but it sounds good to me, and I am going to pay attention to it.

Thank you.

Mr. WEINER. Would the gentlelady yield?

Ms. WATERS. Yes.

Mr. WEINER. This is a scenario where you have the Goliath of PBMs, the Goliath of mail-order, the really big Goliath of the Federal Government, and then the tiny, little, individual people with their tiny, little, individual pharmacists. This might not be the sum and substance, because, at some point, we have to figure out a way to deal with this mail-order explosion, as to whether it is good or bad for health care, but this gives one additional little arrow in the quiver of the community pharmacist to be able to try to deal with things on behalf of their neighbors and their constituents.

So I thank you for keeping an open mind on it, but I think, at the end of the day, we're going to have big health care things we're going to have to do, but this is one way to help community pharmacists survive. So, by the time we get there and Mrs. Clinton is sworn in as President and she starts putting her plans in place, that she has a community pharmacy foundation of providers out there that are still around, because they are precipitously dropping off.

I thank you.

Ms. WATERS. Thank you very much.

Thank you, Mr. Chairman.

Mr. CONYERS. Well, you see, this hearing has been excellent because it raises some larger considerations in the delivery of health care in the United States, and this Committee is poised to make further inquiries.

I just want to congratulate everybody for being here and for being patient. We know that a lot of our colleagues have conflicts, and they will be studying the record carefully.

The gentleman from California, Brad Sherman, has come into the room, and I would yield to him if he wanted to welcome anybody or to make any comments.

Mr. SHERMAN. Thanks for coming here.

I've got a pain here. If you've got some good drugs, that would be helpful. [Laughter.]

I apologize for not being here for the entire meeting, and I'll look forward to studying this issue.

I join with everyone else here on the panel in thinking that Americans need access to a local pharmacist that they can actually talk to.

Thank you.

Mr. CONYERS. And on that note, the Task Force on Antitrust is adjourned. And I thank, again, all of the witnesses for their excellent presentations.

[Whereupon, at 11:23 a.m., the Task Force was adjourned.]